Supreme Court U.S.
FILED

No. 06-___ 061262 MAR 14 2007

OFFICE OF THE CLERK

In The

Supreme Court of the United States

KEITH BAKER, INDIVIDUALLY, AND IAN BAKER, INDIVIDUALLY AND AS INDEPENDENT EXECUTOR OF THE ESTATE OF JEAN BAKER, DECEASED,

Petitioners,

v.

ST. JUDE MEDICAL, S.C., INC., AND ST. JUDE MEDICAL, INC.,

Respondents.

On Petition For A Writ Of Certiorari To The Court Of Appeals Of Texas, First District, Houston

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

Whether the express preemption provision of the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a), was intended by Congress to preempt state-law product liability suits arising from the use of medical devices that have lost their FDA approval.

Whether the Medical Device Amendments were intended by Congress to preempt all state-law injury suits arising from medical devices that have Pre-Market Approval or Pre-Market Supplement Approval.

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INTRODUCTION

A confusing and inconsistent body of law has evolved on the question of when, if ever, the express preemption provision of the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act [MDA], should be recognized as preempting state tort suits arising from the use of an FDA-approved medical device. *See, e.g., Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000) (preemption), and *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999) (no preemption). This situation desperately needs correction.

But suppose a particular device is no longer FDA-approved. Would there be any reason or basis in that circumstance to apply preemption? Clearly not:

> This would be a different case if, prior to the instant litigation, the FDA had . . . taken the necessary steps to remove the harm-causing product from the market. Under those circumstances, respondent's . . . claim would not depend upon speculation as to the FDA's behavior in a counterfactual situation but would be grounded in the agency's explicit actions. . . . If the FDA . . . requires the removal of a product from the market, state damages remedies would not encroach upon, but rather would supplement and facilitate, the federal enforcement scheme.

Buckman v. Plaintiffs' Legal Committee, 531 U.S. 341, 354 (2001) (Stevens, J., concurring).

Yet, that is exactly what the Texas appellate court did here. Jean Baker, the 65 year old mother of the petitioners, died a horrible death in February 2000 as a result of a leak in her heart muscle wall caused by the respondents' defective artificial heart valve. The product was classified

as "defective," "adulterated," and "misbranded," and ordered off the market by the FDA in March 2000.

But the case law on the issue of federal preemption has become so distorted and convoluted in the lower courts that the Texas Court of Appeals felt compelled to hold that preemption applied even as to claims arising from products recognized as defective by the FDA and ordered removed. The appellate court here, just as in all of the other cases in which preemption has been found, clearly engaged in a presumption *in favor* of preemption, rather than *against* preemption.

The upshot of the published opinion in this case is that *every* medical device which has *ever* been approved by the FDA under a Pre-Market Approval [PMA], or a PMA Supplement, is *automatically and forever* exempt from civil liability arising from the use of that device. That could not possibly have been the intent of Congress in passing the MDA. Yet, if this Court does not redirect the lower courts, that is precisely where the majority of published appellate decisions will fall.

This Court should step in and clarify definitively when, if ever, preemption should apply under the MDA. The need is pressing.

OPINION AND ORDER BELOW

The decision of the First District Court of Appeals for the State of Texas is published at *Baker v. St. Jude Medical S.C., Inc.*, 178 S.W.3d 127 (Tex.App. – Houston [1st Dist.] 2005, pet. denied.) Appendix at 1a. The petition for review to the Texas Supreme Court was denied under

Cause Number 06-0223. This type of discretionary denial of a petition for review is not published. Official notification of the denial is reproduced in the Appendix at 22a. The order granting summary judgment which underlies this appeal was entered on April 25, 2002, by Probate Court Number One of Harris County, Texas, in Cause No. 312,543-402 (later severed into Cause No. 312,543-402-A). This order is reproduced in the Appendix at 21a.

JURISDICTION

The petition for review was denied by the Texas Supreme Court on December 15, 2006. Appendix at 22a. This Court has jurisdiction under 28 U.S.C. § 1257.

STATUTES AND REGULATIONS INVOLVED

21 U.S.C. § 331(a) (Due to volume the statutes and rules are reproduced, in accordance with Sup. C. R. 14(1)(f), at Appendix 23a)

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21 C.F.R. § 7.40 (Reproduced at Appendix 26a)

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21 C.F.R. § 870.3925 (Reproduced at Appendix 31a)

21 C.F.R. § 895.1 (Reproduced at Appendix 31a)

STATEMENT OF THE CASE

This petition arises from a state-law wrongful death suit brought in a Texas state court by Keith Baker and Ian Baker, individually and on behalf of the estate of their deceased mother, Jean Baker, against St. Jude Medical, S.C., Inc., and St. Jude Medical, Inc. [SJM]. The petitioners contended that Jean Baker died as the result of a dangerously defective artificial heart valve designed, manufactured, and distributed by SJM.

SJM moved for summary judgment, claiming that, because the subject valve originally had been approved by the FDA under a PMA Supplement, all of the petitioners' claims were preempted by application of the express preemption provision of the MDA, and by the implied preemption doctrine. Appendix at 82a.

The petitioners contended in the trial court that preemption should not be applied to PMA Supplement-approved products in general or with respect to this particular product. The petitioners also contended that the implied preemption doctrine is inapplicable under federal

law. Finally, the petitioners contended that preemption could not possibly apply because this product had been voluntarily withdrawn from the market, and since has been reclassified by the FDA as "defective," "adulterated," and "misbranded," therefore terminating any FDA approval. Absent existing FDA approval, no preemption doctrine can possibly apply.

The petitioners' response to the summary judgment motion was timely filed and relevant portions of the voluminous response are reproduced in the Appendix at 92a. In the court of appeals, the petitioners raised the same contentions, also on a timely basis. The relevant portions of the voluminous briefing filed by the petitioners in that regard are reproduced in the Appendix at 107a. The court of appeals specifically ruled on each of the petitioners' objections. *Baker,* 178 S.W.3d at 134 n.5, 137. These issues were appealed directly by the petitioners to the Texas Supreme Court as well. The relevant portions of the voluminous briefing filed by the petitioners in the Texas Supreme Court are reproduced in the Appendix at 110a.

STATEMENT OF RELEVANT FACTS

In November 1999, Jean Baker was suffering from symptoms of advanced congestive heart failure. Ms. Baker's physicians determined that the patient had a severely leaking cardiac mitral valve, which was causing her problems. CR 928-29.[1]

[1] References to "CR" are to the record in the possession of the Clerk of the First Court of Appeals of Texas. *See,* Sup. C. R. 12(7). As in the federal system, in this state court proceeding the reviewing courts were

(Continued on following page)

Fortunately, prosthetic mitral valves are readily available on the market to correct this malady. Ms. Baker's surgeon selected a market-leading SJM prosthetic mitral valve. CR 2834-35. But, after implant Ms. Baker did not improve. Rather, she deteriorated to a wasting, cachectic state, and finally died in February 2000.

A post-mortem examination revealed that Ms. Baker died as a result of a large hole in her heart, a "paravalvular leak," which had developed where the SJM valve had been sutured to her heart. CR 930-32, 1415-27. Ms. Baker's physicians later learned that they had unknowingly implanted a valve with a new and significant modification – the addition of a thin silver coating to the sewing cuff where it attached to the patient's heart. CR 1401-03.

The original SJM prosthetic mitral valve went through the full PMA process to obtain FDA approval in 1982. CR 2833. This valve generally was successful. However, endocarditis (a cardiac infection), is a rare but known potential complication with every valve replacement surgery. Because silver has anti-microbial qualities in some bodily applications, SJM had the idea that perhaps it could reduce endocarditis by adding a thin silver coating to the fabric sewing cuff. CR 1196. Accordingly, SJM submitted an abbreviated application, known as a "PMA Supplement," to attempt to gain approval to sell its valve with a thin coating of silver, which SJM trademarked as "Silzone." CR 1096-1104.

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required to: "indulge every reasonable inference in favor of the nonmovant, resolve any doubts in its favor, and take as true all evidence favorable to it." *See, Baker,* 178 S.W.3d at 132. *See also, United States v. Diebold, Inc.*, 369 U.S. 654, 655 (1962).

The Silzone-coated valve was allowed to proceed under a significantly abbreviated process than that normally required for prosthetic valve applications. More specifically, the entire application package for the Silzone-coated valve was only about two inches thick. CR 1086-88, 1103. The product also was approved without the usual FDA Expert Advisory Panel review. CR 1086, 1103. The limited animal studies were cut short at SJM's request, and no human studies were considered or required by the FDA. CR 66-67, 1086, 1089-90, 1099, 1104.

The FDA approved the PMA Supplement for the addition of the silver coating on March 30, 1998. CR 1062. However, because SJM was unable to demonstrate the silver coating had any efficacy whatsoever in reducing endocarditis, the FDA prohibited SJM from marketing the product with any such claims. CR 1091. But the company still wanted to market the product as reducing endocarditis. Accordingly, SJM sponsored a post-approval multicenter human study to attempt to determine efficacy of the product in preventing endocarditis. This trial was known as the Artificial Valve Endocarditis Reduction Trial, or "AVERT." CR 1074, 2847.

SJM began receiving reports very early in the AVERT that enrolled patients were experiencing an unexpected number of life-threatening paravalvular leaks adjacent to the area where the Silzone-coated sewing cuffs attached to the patients' heart muscles. CR 1098. In fact, the rate of paravalvular leaks for patients with the Silzone-coated valves was 2%, compared to .25% for patients with conventional valves, an eight-fold increase in risk. *See, In re St. Jude Medical, Inc., Silzone Heart Valves Products Liability Litigation,* MDL No. 01-1396, 2004 U.S. Dist. LEXIS 148,

2004 WL 45503 (D. Minn. January 5, 2004) Appendix at 42a, 45a.[2]

In addition to the patients in the AVERT, Silzone-coated valves were implanted unwittingly in 36,000 other patients worldwide, including Jean Baker. CR 1140. In the meantime, though, evidence from the AVERT of Silzone causing paravalvular leaks became overwhelming. SJM became legally obligated to notify the FDA immediately of these results, as the persistent observed development of paravalvular leaks after implant unquestionably involved a significant threat to the lives of implant recipients. *See,* 21 C.F.R. § 803.10(c). Any notification to the FDA of serious complications arising from the use of an approved device inevitably initiates a mandatory investigation and an FDA enforcement action. *See,* 21 C.F.R. §§ 7.45(a),

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[2] Around the same time this case was filed in state court numerous materially identical cases – involving the same Silzone allegations against SJM – were filed in various federal courts. On April 18, 2001, the federal Judicial Panel on Multidistrict Litigation consolidated and transferred all of these cases and all later "tag-a-long" cases, pursuant to 28 U.S.C. § 1407, to a federal MDL court in the Minnesota District, Hon. John R. Tunheim presiding. *See, In re St. Jude Medical, Inc., Silzone Heart Valves Products Liability Litigation,* No. 1396, 2001 U.S. Dist. LEXIS 5226 (J.P.M.L. April 18, 2001). SJM also filed a preemption summary judgment motion in the MDL, but Judge Tunheim determined none of the claims is preempted by federal law. *See, In re St. Jude Medical, Inc., Silzone Heart Valves Products Liability Litigation*, MDL No. 01-1396, 2004 U.S. Dist. LEXIS at 148, 2004 WL 45503. Appendix at 42a, 78a. Thus, the incongruent impact of the MDL order is that the Silzone-related claims of citizens of all states filed in federal court are not preempted. However, the claims of Texas citizens filing such suits in Texas courts are deemed preempted, by the state court in *Baker,* by application of federal law. In any event, the incidence of paravalvular leaks found by Judge Tunheim was a comparison of the reported incidence of explants due to paravalvular leaks without infection in AVERT patients who received conventional valves compared to those who received Silzone-coated valves (1/394 compared to 8/398). *Id.* Appendix at 42a, 45a.

814.47(2), and 895.1, *et seq. See also, United States v. Superharm Corp.*, 530 F.Supp. 408, 409-10 (E.D. N.Y. 1981).

To avoid this certain prospect, SJM instead initiated a "voluntary recall" of the Silzone-coated valves on January 21, 2000, and simultaneously notified the FDA of this action, as required by law. CR 1120. This type of recall by a manufacturer *only* occurs when the manufacturer recognizes and acknowledges that the recalled products "present a risk of injury or gross deception *or are otherwise defective.*" 21 C.F.R. § 7.40(a) (emphasis added).

The recall notification compelled the FDA to appoint an ad hoc investigative committee. 21 C.F.R. § 7.41(a). Less than 60 days after notification, on March 20, 2000, the unanimous conclusion of the committee was memorialized into a formal memorandum, the "Fitzgerald Memo." Appendix at 33a.

The Fitzgerald Memo noted that FDA now considered the device: "to be *adulterated and misbranded,* because there is a significantly higher rate of paravalvular leaks with the silver ion (Silzone) coated sewing cuffs leading to valve explants."[3] CR 1183-85, 1186-88 (emphasis added).

On March 22, 2000, these determinations were conveyed to SJM by FDA Acting Regional Director Edwin S. Dee (the "Dee Letter"). Appendix at 37a. SJM was formally notified in the Dee Letter that the FDA found the circumstances and actions of SJM met the formal definition for a

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[3] A medical device is deemed "adulterated" only if it is subject to performance standards but fails to conform with such standards, "misbranded" only if it is "health-endangering when used as prescribed." 21 U.S.C. §§ 351(e), 352(j).

"recall." This determination by the FDA was quite significant because it meant that the FDA formally found that the "voluntary recall" was in fact "*an alternative to an FDA legal action to remove the defective products from the market.*" Appendix at 38a (emphasis added).

By law, this meant that SJM's recall was recognized by the FDA as the firm's "removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action, *e.g.*, seizure." *See*, 21 C.F.R. § 7.46(a). In other words, this formal recognition of SJM's act as a statutory "recall" means the FDA would seize these devices, but for the fact that the manufacturer recognized them as defective and voluntarily withdrew them from the market, negating the need for an FDA seizure action. *Id.*

The court of appeals implied that the Silzone-coated valves must still be FDA-approved because the PMA Supplement approval was never formally withdrawn. But this clearly is incorrect. *See, In re St. Jude Medical, Inc., Silzone Heart Valves Products Liability Litigation*, MDL No. 01-1396, 2004 U.S. Dist. LEXIS at 148, 2004 WL at 45503 (Appendix at 42a, 77a):

> The Court hesitates to characterize defendant's argument too harshly, however, it is difficult to read the FDA's March 20, 2000 and/or March 22, 2000 correspondence and find any ambiguity. . . . St. Jude appears to recognize that the Silzone valve is not marketable absent additional approval from the FDA. . . . The Court finds persuasive plaintiffs' argument that the Silzone valve no longer has FDA approval.

But the finding of the Texas Court of Appeals also is a meaningless non-sequitur. It is accurate that the FDA can

initiate formal proceedings to withdraw PMA approval if the Secretary unilaterally finds that products are unsafe, misbranded, adulterated, or defective. 21 U.S.C. § 360e(e)(1). Similarly, the FDA can initiate a recall itself when it determines previously-approved products present a risk of illness, injury, or gross deception. 21 C.F.R. § 7.45(a).

But by specific regulation, an FDA-initiated recall can *only* take place when the manufacturer has not initiated a voluntary recall. 21 C.F.R. § 7.45(a)(2). Indeed, both the approval withdrawal and FDA-initiated recall processes become completely unnecessary when the manufacturer voluntarily recognizes that the products present a risk of injury or gross deception or are otherwise defective, and the FDA reclassifies the products as defective, adulterated, and/or misbranded. 21 C.F.R. § 7.40(a).

This is true because it is a criminal act for any person to introduce into interstate commerce a product that the FDA has found to be either misbranded or adulterated. 21 U.S.C. § 331(a); *In re Grand Jury Subpoena,* 220 F.R.D. 130, 154 (D. Mass. 2004). Moreover, product seizure (or the alternative formal classification of a manufacturer's proposed course as a "recall," as occurred here), is the most drastic non-criminal remedy afforded the FDA, as it also makes further distribution of the product illegal. *See, e.g., Superharm Corp.,* 530 F.Supp. at 409-10.

REASONS FOR GRANTING THE WRIT

There are two compelling reasons this petition for writ of certiorari should be granted by this Court. First, there is a significant conflict in authority with regard to whether suits arising from products approved by the FDA under a PMA or PMA Supplement are ever preempted.

Second, this product is no longer approved by the FDA. Accordingly, there is no reason whatsoever to apply preemption when there is no conflicting FDA approval. Not surprisingly, many product liability suits arise from products which have been found defective, and were therefore withdrawn from the market and divested of FDA approval. The opinion of the Texas Court of Appeals is the only published appellate opinion in this country in which a court has directly addressed this issue. The Texas Court of Appeals erroneously and inexplicably held that preemption always applies, even if the product in issue is no longer FDA-approved. This issue should be resolved definitively by this Court.

These issues will be addressed in reverse order.

A. Preemption When the Product is No Longer FDA-Approved

The Texas Court of Appeals analyzed the issue and held that congressional intent in the MDA is to the effect that, if a medical device once-upon-a-time was FDA approved under any PMA process, then the manufacturer will be forever shielded from any liability arising in any way from the use of that product. *Baker,* 178 S.W.3d at 136-37. Under the *Baker* holding, this would be true *even if the PMA Supplement approval were to be voided, or if it should later be determined that the approval was secured through fraud.* This conclusion is outlandish.

As discussed briefly below, the application of preemption under the MDA has had a curious and confusing history. It is well-settled, however, that the express language of the MDA would compel preemption if: (a) there is an ongoing FDA mandatory design specification; and (b) a state later should pass a regulation mandating a different design. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 487 (1996).

However, the MDA is silent as to whether Congress intended for this preemptive effect also to apply to state common law, developed via case law, or simply to positive statutes or regulations that vary from FDA-imposed obligations.

Case law since 1976 leads to a conclusion that state court judgments in some instances might be considered conflicting requirements so as to invoke express preemption under the MDA and similar statutes. The scope of when these situations might arise was more debatable before the 2005 *Bates* decision, discussed below. However, one aspect of the doctrine has never been subject to debate: The question of whether a state court lawsuit is preempted by the MDA can be determined only by ascertaining whether a state court judgment based on a jury finding could be construed as a "requirement" that conflicts with an existing requirement imposed on the manufacturer by the FDA. *Medtronic,* 518 U.S. at 487.

This analysis assumes that there is some ongoing FDA regulation or finding with which the jury's finding might arguably conflict. Accordingly, it is absurd to suggest that a state court judgment is preempted by the MDA when the product no longer has FDA approval and therefore there is no existing FDA requirement with which the judgment might conflict.

It is important to keep in mind that only an actual, irreconcilable conflict can give rise to preemption:

> As in the typical pre-emption case, the inquiry is whether there exists an irreconcilable conflict between the federal and state regulatory schemes. The existence of a hypothetical or potential conflict is insufficient to warrant the pre-emption of

> the state statute. A state regulatory scheme is not pre-empted . . . simply because in a hypothetical situation a private party's compliance with the . . . [state laws] might cause him to violate . . . [federal] laws.

Rice v. Norman Williams Co., 458 U.S. 654, 659 (1982).[4]

Currently, the only requirements imposed by the FDA with respect to these FDA-determined defective valves are that: (a) all existing stocks be completely and affirmatively removed from the market; and (b) these products no longer be manufactured or sold. Thus, even if a jury verdict in this case could be construed as imposing some type of *requirement*, it is difficult to see how a verdict agreeing with the FDA that the product is defective could possibly conflict with any FDA requirement currently imposed. *Id.*

However, even if one were to analyze this case under the preemption doctrine as if the products were still FDA-approved, the same conclusion against preemption would necessarily be reached under these facts. It is helpful, in analyzing the scope of preemption in this lens, to examine briefly the history of the Medical Device Amendments, as well as the history, purpose, and application of the preemption doctrine.

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[4] Indeed, as quoted at page 1 above, the very situation which faces this Court today – that preemption cannot possibly apply when FDA approval no longer exists – was foreshadowed and analyzed cogently by a member of this Court. *Buckman*, 531 U.S. at 354 (Stevens, J., concurring).

B. Preemption Under the Medical Device Amendments

1. Legislative Background

It was not until 1976 that the federal government decided to regulate medical devices. Prior to that point, the FDA had only limited authority to seize adulterated and misbranded devices already on the market. However, the FDA lacked the authority to prevent the entry of a new medical device. *Medtronic,* 518 U.S. at 476-77.

It became apparent that this regulatory gap had created hazards to the public health and a hodgepodge of medical device regulations imposed by various states to fill the void. Accordingly, Congress enacted the Medical Device Amendments, bringing medical devices for the first time under the approval umbrella of the long-standing Food, Drug, and Cosmetic Act. Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified at 21 U.S.C. § 360c, *et seq.*). From that point forward, it became illegal for anyone to manufacture and distribute any medical device not already on the market without going through FDA approval. 21 U.S.C. § 331(a); *Medtronic,* 518 U.S. at 577.

2. Regulated Medical Device Classifications

To carry out the regulatory function, the MDA set up three classifications for medical devices. Class I devices pose no reasonable risk of illness or injury. They are subject only to minimal regulation by general controls, and do not require pre-approval for distribution. *Medtronic,* 518 U.S. at 476-77 (quoting 21 U.S.C. § 360c(a)(1)(A)).

More potentially harmful devices are designated Class II. These devices also may be marketed without receiving

advance approval from the FDA. *Id.* at 477 (quoting 21 U.S.C. § 360c(a)(1)(B)).

The most potentially harmful devices are designated as Class III devices. All medical devices which present "a potential unreasonable risk of illness or injury," or that are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," are designated Class III. *Id.* (quoting 21 U.S.C. § 360c(a)(1)(C)). All prosthetic heart valves are Class III devices. 21 C.F.R. § 870.3925.

There is a three-tier process for approval of Class III medical devices. The most rigorous process is known as a Premarket Approval, or "PMA." In this process, manufacturers submit detailed information regarding the safety and efficacy of their devices. Animal studies invariably are required, and there are established protocols for these studies with specific devices, including prosthetic heart valves. CR 1099. Most full PMA applications also require extensive human clinical studies before approval can be obtained. *See,* CR 1101-02.

Once this extensive process has been completed, the FDA then carefully reviews each PMA submission in detail. If the submission passes these rigors, an expert review panel typically is appointed for all new PMA applications, to consider and debate the submitted data and to make recommendations to the agency for or against approval. *See,* FDA, *Panel Review for Premarket Approval Applications, May 3, 1996 (P91-2)* ("In general, all PMAs for the first-of-a-kind device should be taken before the appropriate advisory panel for review and recommendation.").

The typical PMA submission takes an average of 1,200 hours of manpower at the FDA. Document submissions in PMA applications typically are counted by the volumes, if not the boxloads. *See, e.g., Horn v. Thoratec Corp.,* 376 F.3d 163, 169-70 (3d Cir. 2004). *See also,* CR 1088. Ultimately, the FDA is authorized to grant premarket approval for a Class III medical device only if the agency finds that there is "reasonable assurance" that the device is "safe and effective." 21 U.S.C. § 360e(d)(2).

An almost painless alternative to the rigors of the full PMA process is the "510k application." This is a very limited form of review that requires manufacturers to submit nothing more than a "premarket notification" to the FDA. The 510k process was created because devices already on the market prior to the passage of the MDA in 1976 did not require approval to continue to be sold. Accordingly, this limited procedure was designed to allow competitive products, which are found to be "substantially equivalent" to such "grandfathered" products, to enter the market without having to go through premarket scrutiny. *Medtronic,* 518 U.S. at 478-79.

Finally, the MDA also permits manufacturers to seek authorization to modify a previously PMA-approved device and avoid the rigorous PMA process, obtaining approval only for the modification through a "PMA Supplement" application. *See,* CR 1102. *See also,* 21 C.F.R. § 814.3(g). The PMA Supplement review can vary significantly with respect to its thoroughness, specificity, and scope. *See,* 32 C.F.R. § 814.3(g). *See also,* CR 1104. By way of example, while a full PMA approval in 1999 took an average of 12 months, the average time for approval of a PMA Supplement application during the same period was only 4 months. Fischell, R.E., *Regulatory Concerns and Issues:*

Have the Bureaucrats Won?, 13 J. INVASIVE CARDIOL. 139-40 (2001).

3. State Regulatory Efforts as Basis for Statement of Preemption in the MDA

During the MDA enactment process, Congress was informed of various states which had stepped into the regulatory vacuum and required that devices undergo state premarket approval before commercial distribution in those states. *Medtronic,* 518 U.S. at 476-77. Because even non-uniform state premarket scrutiny was preferable to no premarket scrutiny at all, Congress allowed state regulatory programs to remain in place or be implemented until the FDA implemented specific counterpart federal regulations. However, those state requirements would thereafter be preempted by the FDA regulation. *Id.*

4. Types of Recognized Federal Preemption

There are three types of federal preemption, one express and two implied. As a result of application of the Supremacy Clause of Article VI, Clause 2, United States Constitution, any state law is preempted when: (1) Congress expressly preempts ("express preemption"); (2) congressional intent to preempt may be inferred from the existence of a pervasive federal regulatory scheme ("implied field preemption"); or (3) state law conflicts with federal law or its purposes ("implied conflict preemption"). *Gade v. National Solid Wastes Mgmt. Ass'n,* 505 U.S. 88, 98 (1992); *English v. General Elec. Co.,* 496 U.S. 72, 78-79 (1990).

Express preemption occurs only when statutory language clearly and explicitly preempts state law. *Hillsborough Co., Fl. v. Automated Med. Labs, Inc.*, 471 U.S. 707, 712-13 (1985).

Implied field preemption occurs only when a federal law encompasses a field so thoroughly that there is no room for the states to supplement the area. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). The question of implied preemption usually does not arise when preemption is expressed in a statute.[5] *Id.* at 517; *Kemp,* 231 F.3d at 222.

The last category, implied conflict preemption, sometimes is recognized because a manufacturer cannot be obligated to comply with a federal regulation that would subject it to liability under state law.[6] *English*, 496 U.S. at 79.

Under any theory, federal law will be deemed to preempt state law only where Congress intended such a result. *Fidelity Federal Sav. And Loan Ass'n v. de la Cuesta,* 458 U.S. 141, 152 (1982). Thus, preemption will be found to exist only where there is a "clear and manifest purpose of Congress" to foreclose a particular field to state legislation. *Jones v. Rath Packing Co.*, 430 U.S. 519, 525

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[5] This is not always the case. However, implied field preemption clearly cannot apply here. *See* pages 20-21, *infra*.

[6] Implied conflict preemption has been addressed in an additional subcategory, where the challenged state law stands as an obstacle to the accomplishment and execution of the objectives of Congress. *Gade*, 505 U.S. at 98. However, this has been recognized as indistinguishable from implied field preemption. *See, Crosby v. National Foreign Trade Council*, 530 U.S. 363, 372 n.6 (2000); *Gade*, 505 U.S. at 115 (Souter, J., dissenting); and *English*, 496 U.S. at 79 n.5.

(1977) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

In this arena, the courts are required to engage in a strong presumption against preemption. *Bates v. Dow AgroSciences, LLC*, 544 U.S. 431, 449 (2005). This presumption is particularly appropriate in light of the fact that the only reference in the MDA which even arguably gives rise to a preemption argument is in § 360k(a), which states *only* that no state can institute or continue in effect any "requirement" that is different from or in addition to any requirement imposed on the product by the FDA. 21 U.S.C. § 360k(a). Significantly, it is only through implication that § 360k(a) has been found to preempt some state court suits, as neither the words nor the legislative history of the statute indicate any such intent. Because there is no clear and unambiguous expression of an intent to preempt civil tort suits in the MDA, the courts are *compelled* to rule against preemption if there is any cogent argument that preemption in the circumstance presented was not intended. *Bates*, 544 U.S. at 449.

5. Inapplicability of Implied Field Preemption

The inclusion of an express preemption provision in a statute does not necessarily preclude application of the doctrine of implied preemption. *Sprietsma v. Mercury Marine*, 537 U.S. 51, 65 (2002). However, in the face of an express preemption provision, the courts should look primarily to the words of the statute. *Id.* at 62-63; *English*, 496 U.S. at 79.

This Court has recognized an appropriate judicial reluctance to expand federal statutes beyond their terms through the doctrine of implied preemption. *See, e.g.*,

Bates, 544 U.S. at 459 (Thomas, J., concurring in part and dissenting in part); *Camps Newfound/Owatonna, Inc. v. Town of Harrison*, 520 U.S. 564, 617 (1997) (Thomas, J., dissenting); and *English,* 496 U.S. at 79. This is based on the fact that preemption must be governed by congressional intent, and the words expressed by Congress in the subject statute are the best gauge of that intent. Otherwise, "a freewheeling judicial inquiry into whether a state statute is in tension with federal objectives would undercut the principle that it is Congress rather than the courts that pre-empts state law." *Gade*, 505 U.S. at 111 (Kennedy, J., concurring in part and concurring in judgment).

With regard to state tort claims brought against manufacturers of defective medical devices, the question of implied field preemption is easily resolved in favor of the petitioners. The federal courts have been quite clear that, when analyzing the preemptive impact of a federal statute with respect to areas traditionally covered by state tort laws, implied field preemption simply does not apply. *See, e.g., Cipollone,* 505 U.S. at 516. *See also, Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984). Thus, reliance on the express preemption language of the MDA to the exclusion of any implied preemption analysis was necessarily and appropriately followed in *Medtronic*, 518 U.S. at 470. This was expressly recognized, first in *Buckman* and later in *Bates*, 544 U.S. at 458 (Thomas, J., dissenting in part and concurring in part).

The claims raised in the case at bar are common law claims, traditionally governed by state law, just as the claims raised in *Bates, Medtronic,* and *Silkwood.* Thus, the doctrine of implied field preemption is inapplicable. *Buckman,* 531 U.S. at 352; *Worthy v. Collagen Corp.*, 967 S.W.2d 360, 368 (Tex.), *cert. denied*, 524 U.S. 954 (1998).

6. *Bates v. Dow AgroSciences, LLC*, and the Impact of Jury Verdicts on Preemption

The express preemption doctrine under the MDA has the identical basis and rationale as implied conflict preemption. *See, e.g., Medtronic,* 518 U.S. at 508 (Breyer, J., concurring). That is, the argument concerning the possible application of the express preemption doctrine under the MDA is premised on the prospect that the manufacturer cannot be expected to continue to design and market a product as required by the FDA, if doing so would subject the manufacturer to liability under state law. *Id. Accord, Riegel v. Medtronic Corp.,* 451 F.3d 104, 122 (2d Cir. 2006); *Horn,* 376 F.3d at 176. Not only is this analysis very firmly supported by *Medtronic*, but it also made some logical sense, as the MDA is completely silent with respect to whether Congress intended to preempt civil lawsuits in any respect. *Medtronic,* 518 U.S. at 491.

There once was a question whether the reference in the MDA to conflicting requirements applied only to positive state enactments, such as statutes and regulations, or could also extend to state common law arising from standards imposed by virtue of lawsuits. That question was first answered affirmatively by this Court in *Cipollone*, 505 U.S. at 507, and recently reaffirmed in *Bates,* 544 U.S. at 443-44.

However, according to this Court, the fact that such a federal statute *might* preempt *some unspecified types* of state court lawsuits:

> says nothing about the *scope* of that pre-emption. For a particular state rule to be pre-empted, it

> must satisfy two conditions. First, it must be a requirement. . . . Second, it must impose a . . . requirement that is "*in addition to or different from*" those required under this subchapter.

Id. (quoting 42 U.S.C. § 369k(a)) (emphasis the Court's).

In *Bates,* the Court was addressing an allegedly preempting provision of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA) (7 U.S.C. § 136, *et seq.*). Texas peanut farmers brought suit against Dow, a pesticide manufacturer, alleging that a pesticide which had been approved by the EPA was nonetheless defective as marketed, and caused damage to their crops. *Bates,* 544 U.S. at 434. Dow moved for summary judgment, contending that the claims were expressly or impliedly preempted by FIFRA. *Id.* at 435. The district court agreed and granted judgment in favor of Dow, which was affirmed by the Fifth Circuit Court of Appeals. *See, Dow AgroSciences, LLC v. Bates,* 332 F.3d 323 (5th Cir. 2003), *rev'd,* 544 U.S. 431 (2005).

The Fifth Circuit held, very similarly to the court of appeals in this case, that a jury verdict would conflict with FIFRA because it would have the tendency to induce the manufacturer to change the marketing of its product to meet the "requirements" implicit in the judgment, rather than the requirements imposed on the product by the EPA. *Compare, Bates,* 332 F.3d at 331 ("For a state to create a labeling requirement by authorizing a claim linked to the specifications of a label, even where the EPA has elected not to impose such labeling requirements, would clearly be to impose a requirement 'in addition to or different from those' required under FIFRA"), *with Baker,* 178 S.W.3d at 137 ("the jury could potentially set a standard of care for

St. Jude that was over and above what the FDA had determined was necessary to produce a safe product.").

But this Court held that the Fifth Circuit was: "*quite wrong* when it assumed that any event, such as a jury verdict, that might 'induce' a pesticide manufacturer to change its label should be viewed as a requirement." *Bates,* 544 U.S. at 443 (emphasis added). The fact that a manufacturer might face a liability judgment, even though its product was approved by a federal regulatory agency, does not mean that the state will have imposed a *conflicting requirement* on the manufacturer. According to the Court:

> A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement.

Bates, 544 U.S. at 445.

Bates explained its distinction from the result reached in *Cipollone.* In *Cipollone,* the plaintiff sued a cigarette manufacturer for alleged defects in cigarette package warnings mandated by federal statute. *Cipollone,* 505 U.S. at 508. The preempting language in issue in that case contained the following language: "No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." *Id.* at 515. The Court held that this language expressly preempted a state court tort claim, which was based on a contention that the cigarette package warnings were inadequate. *Id.* at 521.

But the *Cipollone* Court noted that: "[t]he phrase 'no requirement or prohibition' sweeps broadly and suggests

no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules." *Id.* This was considered important by the *Bates* Court in distinguishing the scope of preemption as to claims brought under FIFRA. *Bates,* 544 U.S. at 447. Under FIFRA and the MDA, the preemption provision only extends to those state *requirements* which are "in addition to or different from" those imposed by the respective federal regulatory agency. *Id.* Thus, the holding of *Cipollone* cannot be extended to claims arising under FIFRA or the MDA. *Id.*

Beyond injunctions, it is not entirely clear after *Bates* exactly when requirements might be deemed imposed by state court suits so as to run afoul of preemption provisions like those in FIFRA or the MDA. However, *Bates* made one point abundantly clear: even if a jury verdict in a damages claim were to be based on a finding that would conflict with an agency finding, the verdict would *never* support application of the preemption doctrine. This is true because the verdict would not be deemed as imposing a *requirement* on the manufacturer as a matter of law. *Id.* at 445. Further, as the *Bates* Court noted, the statutory language of FIFRA is markedly similar to the preemption provision of the MDA. *Id.* at 447. Accordingly, *Bates* clearly commands the same result under the MDA.

7. *Medtronic, Inc. v. Lohr*

Even if analyzed under false premises that: (a) there is some remaining federal approval of the product in issue; and (b) *Bates* did not relegate to historical significance the "conflicting requirements arising from liability exposure"

argument; the result would be the same under clear law before *Bates*.

Until *Bates,* the dispositive case on this issue was the 1996 opinion of this Court in *Medtronic*. But *Bates* did not overrule the holding of *Medtronic*. To the contrary, the *Bates* Court indicated that its unanimous holding against preemption "finds strong support in *Medtronic*." *Bates,* 544 U.S. at 447.

The medical device manufacturer in *Medtronic* sought preemption from state court liability because its product enjoyed continuing FDA approval under the 510k process. 518 U.S. at 486. The defendant manufacturer contended that any medical devices currently approved by the FDA, regardless of route of approval, should be exempt from all state court liability. Medtronic reasoned that the imposition of liability under state court tort standards would conflict with the federal regulation of the devices under the MDA. Thus, the manufacturer argued that state court remedies were expressly or impliedly preempted under 21 U.S.C. § 360k(a). *Id.*

This Court summarily rejected the claim of express and implied "blanket" preemption regardless of route of approval. *Id.* at 486-87. Rather, to determine whether preemption should even be considered, the Court recognized it would be critical to examine exactly what the FDA approved, and how it was approved, against the supposedly conflicting effect of any necessary finding in a state court judgment. *Id.* at 509.

To hold otherwise would act to deprive all persons suffering injuries as a result of a defective device, whom Congress intended to protect in the MDA, of "most, if not all relief." *Id.* at 487. Consequently, this Court refused to

attribute any intent to preempt state tort claims completely, after observing that such blanket preemption would leave the public, the target of the safety concerns of Congress, without a remedy. Hence, the Court stated: "[i]t is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." *Medtronic*, 518 U.S. at 487. This Court logically concluded that the manufacturer's blanket preemption argument: "is not only unpersuasive, it is implausible." *Id.* at 487.

Clearly, a compelling reason for rejection of such blanket preemption claims arose from the Court's recognition that: "the FDA's authority to require manufacturers to recall, replace, or refund defective devices is of little use to injured consumers, since there is no indication that the right is available to private parties, the remedy would not extend to recovery for compensatory damages, and the authority is rarely invoked, if at all." *Id.* at 486 n.7. Subsequently, the Court has recognized the importance of allowing product liability suits against defective products to provide: "an incentive to manufacturers to use the utmost care in the business of distributing inherently dangerous items." *Bates,* 544 U.S. at 450.

The FDA never "required" SJM to put a silver coating on the sewing cuff of its prosthetic heart valves. Thus, even under *Medtronic*, a verdict based on a finding that the silver coating was defective in design could not possibly conflict with any requirement imposed by the FDA. *Medtronic*, 518 U.S. at 487. The fact that this medical device was approved under a PMA or a PMA supplement, rather than a 510k application, makes SJM's blanket preemption argument no more persuasive or plausible than it was in *Medtronic*.

CONCLUSION

The majority of the lower courts have gone far afield from the regulatory preemption language in the MDA to curtail all rights of recourse for innocent victims injured by defective medical devices. This was caused, in part, by the fact that *Medtronic* did not present this Court with an opportunity to address preemption with respect to devices approved through means other than a 510k. By contrast, the instant case presents this Court with a very good clarification opportunity.

Here, the unjustified judicial expansion of the preemptive effect of the MDA has been extended to devices that are no longer approved by the FDA. The willingness of the Texas appellate courts to distort this Court's ruling in *Medtronic* to reach such a clearly improper result illustrates the pressing need of the lower courts for further directive as to the scope of such preemption.

This petition for a writ of certiorari should be granted.

Respectfully submitted,

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March 2007

No. 06-___

In The Supreme Court of the United States

KEITH BAKER, INDIVIDUALLY, AND IAN BAKER, INDIVIDUALLY AND AS INDEPENDENT EXECUTOR OF THE ESTATE OF JEAN BAKER, DECEASED,

Petitioners,

v.

ST. JUDE MEDICAL, S.C., INC., AND ST. JUDE MEDICAL, INC.,

Respondents.

On Petition For A Writ Of Certiorari To The Court Of Appeals Of Texas, First District, Houston

APPENDIX

KEITH BAKER, INDIVIDUALLY, AND IAN BAKER, INDIVIDUALLY AND AS INDEPENDENT EXECUTOR OF THE ESTATE OF JEAN BAKER, DECEASED, Appellants v. ST. JUDE MEDICAL, S.C., INC. AND ST. JUDE MEDICAL, INC. Appellees

NO. 01-02-00802-CV

COURT OF APPEALS OF TEXAS, FIRST DISTRICT, HOUSTON

178 S.W.3d 127; 2005 Tex. App. LEXIS 5135

June 30, 2005, Filed

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JUDGES: Panel consists of Chief Justice Radack and Justices Jennings and Higley.

OPINION BY: Sherry Radack, Chief Justice.

OPINION:

This appeal involves the issue of federal preemption of state law causes of action arising out of the implantation of an allegedly defective heart valve in the deceased, Jean Baker. Specifically, we must decide whether state common-law causes of action asserted by Baker's heirs against the valve manufacturer are preempted by the manufacturer's compliance with the Food and Drug Administration's premarket approval procedures for certain medical devices. Because we hold that state product-liability claims

are preempted by federal law in this case, we affirm the summary judgment granted in the manufacturer's favor.

BACKGROUND

Legislative Background of Medical Devices Act

In 1976, in response to mounting consumer concern over, among other things, defective intrauterine devices, Congress passed the Medical Device Amendments (MDA) to allow the Food and Drug Administration (FDA) to regulate medical devices. The MDA creates three categories of medical devices. The most stringent FDA control is over Class III devices, which are devices that either "present a potential or unreasonable risk of illness or injury," or which are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." *See* 21 U.S.C. § 360c(a)(1)(C)(ii)(I-II). It is undisputed that a heart valve is a Class III medical device.

Obtaining FDA Approval to Market Class III Devices

1. Full PMA Approval

Before marketing a Class III device, the manufacturer must either submit its product to the FDA for premarket approval (PMA) or qualify for one of two exceptions to the premarket approval process. To obtain PMA approval, the manufacturer must provide the FDA with "reasonable assurance" that the device is safe and effective. *See* 21 U.S.C. § 360e(d)(2). To do so, manufacturers submit detailed information regarding their device, which the FDA then reviews for an average of 1200 hours before

approving or disapproving the device. *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 477, 116 S. Ct. 2240, 2247, 135 L. Ed. 2d 700 (1996).

2. § 510(k) Exemption to PMA approval

In addition to the "rigorous" PMA process, there are two exemptions by which a manufacturer may gain the FDA's permission to market a device. *Id.* at 477-78, 116 S. Ct. at 2247. One of these exemptions permits devices that are "substantially equivalent" to devices existing in 1976[1] to be marketed and sold without full PMA approval. *See* 21 U.S.C. § 360j(g)(1). This review is known as a section 510(k) review (after the number of the section in the original act) and is "by no means comparable to the PMA process." *Lohr,* 518 U.S. at 479, 116 S. Ct. at 2247. As opposed to the PMA's average review time of 1200 hours, a § 510(k) review takes an average of only 20 hours to complete. *Lohr,* 518 U.S. at 478, 116 S. Ct. at 2247.

3. PMA Supplementation for Modifications to PMA-Approved Devices

If a manufacturer wants to modify a Class III device that already has PMA approval, the manufacturer may submit a PMA supplement, rather than obtain an entirely

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[1] The MDA includes a "grandfathering" clause, which allows pre-1976 devices to remain on the market until such time as the FDA initiates and completes PMA approval. *See* 21 U.S.C. § 360e(b)(1)(A). The MDA also contains an investigational device exemption (IDE), which permits unapproved devices to be used in human trials. *See* 21 C.F.R. § 812.1. Neither the grandfathering clause or the IDE exemption is relevant to this case.

new PMA approval. *See U.S. v. Prigmore,* 243 F.3d 1, 5 (1st Cir. 2001) (describing PMA supplement process). The PMA supplement "must contain scientific information that provides a basis for approval of the modified device." *Id.* (quoting 21 C.F.R. § 814.39(c)). The procedures for a PMA supplement are the same as those for an original PMA, although the FDA requires only that the manufacturer provide materials supporting the proposed modification. *Worthy v. Collagen Corp.,* 967 S.W.2d 360, 364-65, 41 Tex. Sup. Ct. J. 424 (Tex. 1998); *Kemp v. Medtronic., Inc.,* 231 F.3d 216, 222 (6th Cir. 2000).

Factual Background

In 1982, the FDA approved St. Jude's initial PMA application for a mechanical heart valve. During the following years, St. Jude made several improvements to the valve, which were approved through a series of PMA supplements. One of these improvements incorporated a rotating sewing cuff, which eliminated the need for surgery to position the valve before sewing it in place.

In an effort to combat endocarditis, a life-threatening infection of the heart muscle,[2] St. Jude notified the FDA that it planned to develop a mechanical heart valve with an infection-resistant, sterile, silver coating on the sewing cuff. In May 1997, after an FDA-required animal test was

[2] The record shows that the decedent, Baker, was suffering from endocarditis before her valve replacement surgery. Endocarditis is fatal in 25% to 60% of those suffering from it.

completed, St. Jude submitted a PMA supplement to add the Silzone[3] coating to its already approved heart valve.

In March 1998, the FDA approved St. Jude's PMA supplement. As part of its approval, the FDA imposed several post-approval requirements, including how the valve could be marketed. Specifically, the FDA prohibited St. Jude from making any claims about the efficacy of the Silzone coating in preventing endocarditis. St. Jude began marketing the Silzone valve accordingly.

St. Jude, however, continued to participate in studies to determine the efficacy of the Silzone coating in preventing endocarditis. One of these studies was the Artificial Valve Endocarditis Reduction Trial (AVERT). On January 21, 2000, approximately one month before Baker's death, an independent board reviewing the AVERT data concluded that patients with the Silzone valve were more likely to experience a post-operative complication known as a paravalvular leak. Approximately 2% of the patients with the Silzone valve experienced such leaks, as opposed to .25% of patients with conventional valves.

The same day that it became aware of the conclusions of the AVERT monitoring board, St. Jude began a voluntary recall of all non-implanted Silzone valves, and so informed the FDA. In response, the FDA, in a letter from Edwin Dee to St. Jude, stated, "We agree with your firm's decision to recall [the Silzone valve] . . . We have reviewed your action and conclude that it meets the formal definition of a 'Recall.' "This is significant, as your action is an alternative to a Food and Drug Administration legal action

[3] Silzone® is the trademark name for the sterile, silver coating that St. Jude added to the sewing cuff of its heart valve.

to remove the defective products from the market."[4] It is undisputed, however, that the FDA never formally withdrew its PMA approval of the valve, and that the valve had FDA approval on the date it was implanted in Baker.

The decedent in this case, Jean Baker, a 66-year-old woman, had undergone open heart valve-replacement surgery in November 1999. A Silzone-coated heart valve, manufactured by St. Jude, was implanted in Baker to replace her own deteriorating mitral heart valve. In February 2000, approximately one month after St. Jude issued its voluntary recall of the valves, Baker died.

Baker's two sons, Ian Baker and Keith Baker, filed this wrongful death suit against St. Jude based on theories of negligence, product liability, breach of warrant under the *Deceptive Trade Practices Act*, malice, and fraud. St. Jude filed a motion for summary judgment, contending that the appellee's state court claims were preempted by the FDA's federal regulation over the valves at issue. The trial court agreed, and granted St. Jude's motion for summary judgment.

ANALYSIS

Standard of Review for Summary Judgments

We will uphold a summary judgment only if the record establishes that there is no genuine issue of material fact, and that the movant is entitled to judgment as a matter of

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[4] Appellants contend that the trial court erred in granting St. Jude's objection to the Dee letter and to another FDA memo, in which an FDA official referred to the Silzone valve as "misbranded" or "adulterated." We do not find the admissibility of this evidence to be a deciding factor in this case (*see* fn. 5).

law on a ground set forth in the motion. *See* TEX. R. CIV. P. 166a(c); *Cathey v. Booth,* 900 S.W.2d 339, 341, 38 Tex. Sup. Ct. J. 927 (Tex. 1995). In reviewing the summary judgment, we indulge every reasonable inference in favor of the non-movant, resolve any doubts in its favor, and take as true all evidence favorable to it. *Pace v. Jordan,* 999 S.W.2d 615, 619 (Tex.App. – Houston [1st Dist.] 1999, pet. denied).

Preemptive Effect of PMA Approval

1. Can a State-Court Action be a Prohibited State "Requirement"?

State laws that conflict with federal laws are preempted under the Supremacy Clause of the Constitution. U.S. CONST. Art. VI, cl. 2. Congressional intent to preempt state law can either be expressly stated in statutory language or implied in the structure and purpose of federal law. *Cipollone v. Liggett Group, Inc.,* 505 U.S. 504, 516, 112 S. Ct. 2608, 2617, 120 L. Ed. 2d 407 (1992). The MDA contains an express preemption provision, which provides as follows:

> *No State* or political subdivision of a State *may establish* or continue in effect with respect to a device intended for human use *any requirement* –
>
> > (1) *which is different from, or in addition to,* any *requirements applicable under this [Act]* to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this [Act].

21 U.S.C. § 360k (emphasis added). The initial issue, thus, is whether a state tort lawsuit can ever be a state "requirement," prohibited by § 360k.

The Supreme Court considered this issue in *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996). In *Lohr,* the Supreme Court held that state-tort claims were not preempted if a medical device received FDA approval through the § 510(k) notification process. The majority noted that, under § 510(k) approval process, the FDA makes no endorsement as to a product's safety, but concludes only that it is "substantially equivalent" to a device already on the market. The Court concluded that because a § 510(k) approval by the FDA did not impose any federal requirements, any requirement imposed by the states was not prohibited. 518 U.S. at 493-94, 116 S. Ct. at 2254-55.

The *Lohr* court, however, could not agree on whether a state-court action could ever be considered a state "requirement." Four justices of the majority (Stevens, Kennedy, Souter, and Ginsburg) could not accept "Medtronic's argument that by using the term 'requirement,' Congress clearly signaled its intent to deprive States of any role in protecting consumers from the dangers inherent in many medical devices." 518 U.S. at 489, 116 S. Ct. at 2252.

This portion of the *Lohr* opinion, however, was not supported by a majority of the members of the Court. The dissenting justices (O'Connor, Rehnquist, Scalia, and Thomas) concluded that "a fair reading of § 360k indicates that state common-law claims are preempted, as the statute itself states, to the extent that their recognition would impose 'any requirement' different from, or in addition to, FDCA requirements applicable to the device."

518 U.S. at 512, 116 S. Ct. at 2263 (O'Connor, J., dissenting).

Justice Breyer also refused to join the portion of the opinion holding that § 360k did not prohibit state-court actions because he was "not convinced that future incidents of MDA preemption of common law claims will be 'few' or 'rare'." 518 U.S. at 508, 116 S. Ct. at 2261-62 (Breyer, J., concurring). Justice Breyer concluded that, "insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action." 518 U.S. at 504-05, 116 S. Ct. at 2260.

As we read *Lohr,* a majority of the justices of the Supreme Court would hold that a state-court tort claim can be expressly preempted by § 360k of the MDA. Since *Lohr,* a majority of the federal courts considering the issue have agreed. *See Horn v. Thoratec Corp.,* 376 F.3d 163, 176 (3rd Cir. 2004) (holding that state common law claims and duties were preempted because they were "in severe tension with" requirements established by FDA in approving device); *Martin v. Medtronic, Inc.,* 254 F.3d 573, 585 (5th Cir. 2001) (holding that "a medical device manufacturer's compliance with the FDA's PMA process will preempt state tort law claims with respect to that approved device and relating to safety, effectiveness or other MDA requirements when the substantive requirements imposed by those claims potentially conflict with PMA approval."); *Kemp v. Medtronic, Inc.,* 231 F.3d 216, 230 (6th Cir. 2000); *Mitchell v. Collagen Corp.,* 126 F.3d 902, 913-14 (7th Cir. 1997); *Brooks v. Howmedica, Inc.,* 273 F.3d 785, 796 (8th Cir. 2001); *Papike v. Tambrands, Inc.,*

107 F.3d 737, 742 (9th Cir. 1997); *but see Oja v. Howmedica, Inc.*, 111 F.3d 782, 789 (10th Cir. 1997) (common-law failure to warn claim is not subject to preemption under the MDA); *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999) (holding that simple approval of a PMA application imposes no federal "requirements"); *In re St. Jude Medical, Inc.*, 2004 U.S. Dist. LEXIS 148, 2004 WL 45503, *10 (D. Minn. Jan. 5, 2004) (same).

Importantly, the Texas Supreme Court has held that "a federal requirement concerning a device *can preempt* a suit in which the claim is that the device should have been made or marketed differently provided . . . the federal requirement is sufficiently specific." *Worthy v. Collagen Corp.*, 967 S.W.2d 360, 371, 41 Tex. Sup. Ct. J. 424 (Tex. 1998) (emphasis added).

The Supreme Court has recently reaffirmed that a "requirement" can reach beyond positive enactments, such as statutes and regulations, to embrace common-law duties. *Bates v. Dow Agrosciences, L.L.C.*, 544 U.S. 431, 161 L. Ed. 2d 687, 125 S. Ct. 1788, 1798 (2005). "A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement." *Id.* at 1799. Like the preemption clause in *Bates*, § 360k prohibits requirements that are *different from, or in addition to* those provided in the federal act. A state-law requirement is not preempted if it is equivalent to, and fully consistent with, the federal act. *See id.* at 1800.

Based on the authorities cited above, we conclude that state-tort claims can impose prohibited state "requirements" under § 360k of the MDA if a jury award on the cause of action would conflict with or add to a specific

requirement set by the FDA for the device at issue. That is, if a jury award on the asserted cause of action could potentially set a standard of care different from that specifically set by the FDA, the state law cause of action would constitute a prohibited state-law "requirement." Accordingly, we disagree with appellants' assertion that their lawsuit merely seeks "remedies," but does not impose any additional state "requirements."[5]

2. *Does the PMA/PMA Supplement Process Impose Federal Requirements?*

The issue of whether a state law cause of action imposes a state requirement is irrelevant if there is no federal requirement to preempt the state requirement. In *Lohr,* the Supreme Court held that, under the less rigorous § 510(k) approval process there was no federal requirement imposed because the FDA makes no endorsement as to a product's safety, but concludes only that it is "substantially equivalent" to a device already on the market. Thus, the Court concluded that a § 510(k) approval by the FDA did not impose any federal requirements. 518 U.S. at 493-94,

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[5] We likewise disagree with appellants' assertion that preemption, if applicable, evaporates if the FDA later determines that the PMA approval was wrongly granted. Appellants cite no authority for this position. The issue is whether, at the time the device was implanted, it was covered by PMA approval. Whether St. Jude was in compliance with federal requirements setting the standard of care at the time the alleged tort was committed is appropriate issue. *See Carey v. Shiley,* 32 F. Supp. 2d 1093, 1095 (S.D. Iowa 1998) (preemption appropriate in suit involving PMA-approved device although product was later withdrawn from market). It is undisputed that, in this case, the Silzone valve, at the time it was implanted in Baker, had been approved by the FDA through both a PMA and a PMA supplement.

116 S. Ct. at 2254-55. There being no federal requirement, no issue of preemption was raised.

Appellants argue that, like the 510(k) process evaluated in *Lohr,* the PMA supplement process is too "abbreviated" to have imposed any "federal requirements." In support, appellants argue that the PMA Supplement took only 10 months to obtain and the entire file for the supplement is only 2 inches thick.

We disagree with appellants' characterization of the PMA supplement process as "abbreviated." In *Kemp v. Medtronic,* the Sixth Circuit considered an argument that the PMA supplement process was less rigorous than the initial PMA approval process. 231 F.3d at 227. The court noted that

> [t]his distinction [between the rigors of an initial PMA and a PMA Supplement] is readily understandable because a PMA requires review of a previously unapproved device that does not qualify for exemption either as substantially equivalent to devices extant in 1976 or as in IDE. By contrast, a PMA Supplement proposes changes to a device that has already received rigorous review and approval during the original PMA process. Hence, because the FDA has already made a determination as to the safety and effectiveness of the underlying device in the original PMA, it can evaluate only the proposed modifications presented in the PMA Supplement while relying on its earlier approval of the original device.

Id. Similarly, a federal district court in Texas has adopted the reasoning of *Kemp* and held that "for purposes of a preemption analysis . . . there is no difference between the PMA process and the PMA Supplement process." *In re*

Medtronic Polyurethane Insulated Pacing Lead Prod. Liability Litigation, 96 F. Supp. 2d 568, 570 (E.D. Tex. 1999). In fact, the federal regulations applicable to PMA supplements provide that "all procedures and actions that apply to an application under [an initial PMA] also apply to PMA supplements except that the information required in a supplement is limited to that needed to support the change." 21 C.F.R. § 814.39(c).

There is no categorical distinction between a device approved solely on a PMA application and a device that has been approved through a PMA application coupled with a subsequent PMA supplement. If we were to accept appellants' argument that the PMA supplement must itself be as exhaustive as the initial PMA, there would be no need for PMA supplements. Rather, an entire new PMA application would be required for each product innovation. Therefore, in analyzing whether the PMA approval process is sufficient to support a finding that federal regulations were imposed, we believe that we must look at the initial PMA and the PMA Supplement together. Thus, the proper inquiry is to consider the initial PMA application and the PMA supplement, as a whole, in determining whether federal requirements have been imposed.

In concluding that PMA approval imposed federal requirements, the *Worthy* court considered the specificity of the manufacturer's presentation to the FDA, the amount of time required to obtain approval, the recurrence of the investigation a decade later, the prohibition against deviation from the conditions of approval, and the FDA's specific finding that the product was "safe and effective." 967 S.W.2d at 376.

We find many of these same factors present in this case. St. Jude's submissions to the FDA in connection with the initial PMA included detailed information about its intended use, manufacturing methods, design, testing, labeling, etc. The FDA imposed specific conditions, including the required labeling for the valve. The FDA imposed precise manufacturing standards. The initial PMA application took nearly two years to complete.

The PMA Supplement process, which addressed only the addition of the silver coating to the sewing cuff, was equally as exacting and took an additional 10 months. The FDA required that St. Jude conduct certain animal tests, which St. Jude conducted before ever submitting its PMA Supplement application. St. Jude's PMA supplement application included detailed information regarding how the silver coating would be manufactured. Specifically, a coating of silver 0.4 microns thick would be applied to the rotating cuff by using an ion beam to assist the deposition process. The application further stated that the manufacturing process for the Master Series mechanical heart valve with and without Silzone was identical, with the exception of the silver coating. In four amendments to its PMA Supplement application, St. Jude, at the request of the FDA, provided further substantiation regarding the benefits of the silver cuff, labeling changes regarding the effectiveness of reducing endocarditis in humans, revisions to a proposed clinical study, and information regarding corrosion issues that had been raised by an FDA expert. St. Jude's final amendment to its PMA Supplement application included a detailed explanation of the sewing cuff attachment mechanism, a discussion of the manufacturing and assembly process, and a discussion regarding corrosion issues.

Finally, some 10 months after St. Jude filed the PMA Supplement application and over two years after initially proposing the silver cuff to the FDA, the FDA approved the PMA Supplement for the Masters Series valve with the Silzone coating. The FDA's approval was conditioned on certain labeling, including a requirement that, when the term "Silzone" was used, that it be followed by an asterisk that directed the reader to a prominently placed footnote explaining that no clinical studies were performed to evaluate the effect of the Silzone coating in reducing the incidence of endocarditis.

Like the *Worthy* court, we conclude that the FDA's approval of the PMA supplement device constituted a finding that the device, as modified, was "safe and effective," *see* 21 U.S.C. at § 360e(d)(2), although the FDA did not allow St. Jude to make any claims about its effectiveness in preventing endocarditis.[6] This conclusion is supported by the FDA's own words in its letter approving the PMA Supplement, wherein the FDA notes that further PMA Supplements are required whenever a "device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device *remains* safe and effective." (Emphasis added).

Accordingly, we hold that the PMA approval process that St. Jude went through in obtaining FDA approval, including both the initial application process and the PMA Supplement process for the Silzone-coated cuff, was sufficiently specific to impose federal requirements on St.

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[6] Ms. Baker's death was allegedly caused by a paravalvular leak, not endocarditis.

Jude regarding the manufacture and labeling of the heart valve.

2. *Are Appellants' State-Court Causes of Action Prohibited "Requirements"?*

Having decided that state-tort claims can be prohibited state "requirements" under § 360k, and that the PMA and PMA Supplement process imposed federal requirements in this case, we must now decide whether appellants' state-law claims impose requirements that potentially conflict with or add to the FDA's requirements. To do so, we examine the allegations made under each cause of action.

A. Negligence/Products Liability/DTPA

In their petition, appellants contend that St. Jude was negligent in the design, manufacture, and marketing of the Silzone valve. Under their products-liability claims, the appellants contend that the Silzone valve was unreasonably dangerous and defective and was defectively manufactured. Under their DTPA claim, appellants allege that St. Jude made promises and express warranties that the product was safe and that there were implied warranties of merchantability and fitness in connection with the product. In sum, the appellants' claims all require them to prove that the Silzone valve was not safe.

In *Worthy,* the Texas Supreme Court considered whether preemption applied to a product that had been approved by the FDA through a PMA application and following PMA supplement. 967 S.W.2d at 364-65, 376-77. The plaintiff in that case brought DTPA claims, asserting that the product, Zyderm, was unsafe for her use. Such a

finding, the court noted, would "contradict not only the FDA's specific finding to the contrary but also the manufacturing, distribution, and labeling protocols approved by the FDA." *Id.* at 376. The court also noted that there was "no difference in substance" between the plaintiff's claims under the DTPA or "common law claims for negligence, breach of warranty, and products liability." *Id.*

Based on *Worthy,* we conclude that appellants' claims for negligence, products liability, and DTPA violations are preempted because they would require a finding that the Silzone valve was unsafe, a direct contradiction to the PMA approval and PMA supplemental approval granted by the FDA. In other words, the jury could potentially set a standard of care for St. Jude that was over and above what the FDA had determined was necessary to produce a safe product. The FDA had set specific manufacturing and labeling requirements that cannot be altered by a jury's potential finding that another manufacturing process would have been safer or another label clearer. Thus, we hold that appellants' negligence, products liability, and DTPA claims are expressly preempted under § 360k.

B. Fraud/Malice

The appellants also allege that St. Jude committed fraud and acted with malice because it did not report certain adverse events involving Silzone valves before issuing its voluntary recall, even though the FDA had mandated that it do so.[7] Appellants argue that, because

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[7] In March 1998, when the FDA approved the PMA Supplement to add the Silzone coating to the sewing cuff of the valve, it did so on the condition that St. Jude: (1) not market the product with any claim or implication that the Silzone coasting was effective in the prevention of

(Continued on following page)

these claims rely on the enforcement of a federal requirement, they are not "additional" state requirements.

We agree that claims based on a manufacturer's failure to follow the FDA's regulations and procedures in manufacturing and marketing a device are not preempted. *Martin,* 254 F.3d at 583. "Nothing in § 360k denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Lohr,* 518 U.S. 470, 495, 116 S. Ct. 2240, 135 L. Ed. 2d 700. Appellants contend that St. Jude knew of adverse effects at the time of Baker's implant, but did not report them to the FDA until the AVERT study was completed. Appellants argue that St. Jude's failure to make these reports, as required by the FDA, gave rise to a common-law cause of action for fraud and also shows malice.

St. Jude, however, contends that this is essentially a "fraud-on-the-FDA" claim, which the Supreme Court has

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endocarditis; (2) submit post-approval reports to the FDA at intervals of one a year; (3) carefully track, to the final user or patient, each device so that they could be located quickly is [sic] serious problems were determined to be occurring with the product; (4) submit a new PMA Supplement when any unanticipated adverse effect, increase in the incidence of adverse effect, or device failure, was encountered; (5) submit, within 10 days of having knowledge, any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that was attributable to the device; and (6) report any time [appellees] received or otherwise became aware of any information from any source, that suggested that the device may have caused or contributed to a serious death or injury, or had malfunctioned such that it could be likely to cause or contribute to a death or serious injury if the malfunction were to recur, within 30 days of becoming aware of a reportable death, injury, or malfunction, or within 5 days of becoming aware that a reportable event required remedial action to prevent an unreasonable risk of substantial harm to the public.

held is preempted. In *Buckman v. Plaintiffs' Legal Committee,* 531 U.S. 341, 121 S. Ct. 1012, 1015, 148 L. Ed. 2d 854 (2001), the plaintiffs contended that the defendant made misrepresentations to the FDA to secure PMA approval for the product at issue, and that, but for those misrepresentations, FDA would not have approved the product and the plaintiffs would not have been injured. 531 U.S. at 343, 121 S. Ct. at 1015. The Supreme Court concluded that "policing fraud against federal agencies is hardly 'a field which the States have traditionally occupied,'" and held that the plaintiffs' claims arising out of misrepresentations made to the FDA were "impliedly preempted." 531 U.S. at 347, 348, 121 S. Ct. at 1017. Such claims, the court held, "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administrations judgment and objectives." 531 U.S. at 350, 121 S. Ct. at 1018. The Supreme Court noted that "although [*Lohr*] can be read to allow certain state-law causes of action that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state law claim." 531 U.S. at 353, 121 S. Ct. at 1020.

We also note that the FDA has the tools necessary to police and punish those who conceal or fail to report information. As the Court detailed in *Buckman,*

> The FDA is empowered to investigate suspected fraud, *see* 21 U.S.C. § 372; 21 CFR § 5.35 (2000), and citizens may report wrongdoing and petition the agency to take action, § 10.30. In addition to the general criminal proscription on making false statements to the Federal Government, 18 U.S.C. § 1001 (1994 ed., Supp. V), the FDA may respond to fraud by seeking injunctive relief, 21 U.S.C. § 332, and civil penalties, 21 U.S.C. § 333(f)(1)(A);

> seizing the device, § 334(a)(2)(D); and pursuing criminal prosecutions, § 333(a). The FDA thus has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud upon the Administration.

531 U.S. at 349, 121 S. Ct. at 1017-18 (footnote omitted).

In this case, appellants' fraud claim is not based on a "parallel federal safety requirement." Rather, appellants are essentially alleging that St. Jude withheld, or unreasonably delayed, in providing the FDA with information that it had regarding adverse effects associated with the Silzone valve. As such, we hold that appellants' fraud claim is really a "fraud-on-the-FDA claim," and is, therefore, impliedly preempted.

CONCLUSION

Because we have held that all of appellants' claims are preempted by federal law, we affirm.

Sherry Radack

Chief Justice

CAUSE NO. 312543-401
(Consolidated)

ESTATE OF	§	**IN THE PROBATE COURT**
JEAN BAKER	§	**NUMBER ONE (1) OF**
DECEASED	§	**HARRIS COUNTY, TEXAS**

ORDER

(Filed Apr. 25, 2002)

The Court has considered St. Jude Medical's Motion For And Brief In Support Of Motion For Summary Judgment.

IT IS ORDERED that the St. Jude Medical's Motion For and Brief In Support Of Motion for Summary Judgment is **GRANTED**; and that Plaintiff take nothing from St. Jude Medical.

SIGNED this 25th day of April, 2002.

/s/ Russell Austin
JUDGE PRESIDING

[SEAL] OFFICIAL NOTICE FROM
SUPREME COURT OF TEXAS
Post Office Box 12248
Austin, Texas 78711-2248 DATE: 12/15/2006

RE: Case No. 06-0223
COA #: 01-02-00802-CV ID#: 312543-401

STYLE: KEITH BAKER, INDIVIDUALLY AND IAN BAKER, INDIVIDUALLY AND AS INDEPENDENT EXECUTOR OF THE ESTATE OF JEAN BAKER, DECEASED v. ST. JUDE MEDICAL, S.C., INC., AND ST. JUDE MEDICAL, INC.

Today the Supreme Court of Texas denied the petition for review as amended in the above-referenced case.

MAIL TO:

MR. TIMOTHY D. RILEY
RILEY LAW FIRM
112 E 4TH STREET
HOUSTON TX 77007

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21 U.S.C. § 331(a) provides in part:

The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

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21 U.S.C. § 351(e) provides in part:

Adulterated drugs and devices

A drug or device shall be deemed to be adulterated –

* * *

(e) Devices not in conformity with performance standards.

(1) If it is, or purports to be or is represented as, a device which is subject to a performance standard established under section 514 [21 USCS § 360d], unless such device is in all respects in conformity with such standard.

(2) If it is declared to be, purports to be, or is represented as, a device that is in conformity with any standard recognized under section 514(c) [21 USCS § 360d(c)] unless such device is in all respects in conformity with such standard.

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21 U.S.C. § 352(j) provides in part:

Misbranded drugs and devices

A drug or device shall be deemed to be misbranded –

(j) Health-endangering when used as prescribed. If it is dangerous to health when used in the dosage, or manner

or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

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21 U.S.C. § 360c(a)(1)(C) provides in part:

Classification of devices intended for human use

(a) Classes of devices.

(1) There are established the following classes of devices intended for human use:

* * *

(C) Class III, premarket approval. A device which because –

(i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and (II) cannot be classified as a class II device because insufficient information exists to determine that the special controls described in subparagraph (B) would provide reasonable assurance of its safety and effectiveness, and

(ii) (I) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or

(II) presents a potential unreasonable risk of illness or injury,

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21 U.S.C. § 360e(d)(2) provides in part:

(2) The Secretary shall deny approval of an application for a device if, upon the basis of the information submitted to the Secretary as part of the application and any other information before him with respect to such device, the Secretary finds that –

(A) there is a lack of a showing of reasonable assurance that such device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

(B) there is a lack of a showing of reasonable assurance that the device is effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof. . . .

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21 U.S.C. § 360e(e)(1) provides in part:

Withdrawal and temporary suspension of approval of application.

(1) The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from a panel or panels under section 513 [21 USCS § 360c], and after due notice and opportunity for informal hearing to the holder of an approved application for a device, issue an order withdrawing approval of the application if the Secretary finds –

(A) that such device is unsafe or ineffective under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

(B) on the basis of new information before him with respect to such device, evaluated together with the evidence available to him when the application was approved, that there is a lack of a showing of reasonable assurance that the device is safe or effective under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

(C) that the application contained or was accompanied by an untrue statement of a material fact;

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21 U.S.C. § 360k(a) provides in part:

State and local requirements respecting devices

(a) General rule. Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –

(1) which is different from, or in addition to, any requirement applicable under this Act [21 USCS §§ 301 et seq.] to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act [21 USCS §§ 301 et seq.].

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21 C.F.R. § 7.40 provides in part:

Recall policy.

(a) Recall is an effective method of removing or correcting consumer products that are in violation of laws administered by the Food and Drug Administration. Recall is a

voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective. This section and §§ 7.41 through 7.59 recognize the voluntary nature of recall by providing guidance so that responsible firms may effectively discharge their recall responsibilities. These sections also recognize that recall is an alternative to a Food and Drug Administration-initiated court action for removing or correcting violative, distributed products by setting forth specific recall procedures for the Food and Drug Administration to monitor recalls and assess the adequacy of a firm's efforts in recall.

(b) Recall may be undertaken voluntarily and at any time by manufacturers and distributors, or at the request of the Food and Drug Administration. A request by the Food and Drug Administration that a firm recall a product is reserved for urgent situations and is to be directed to the firm that has primary responsibility for the manufacture and marketing of the product that is to be recalled.

(c) Recall is generally more appropriate and affords better protection for consumers than seizure, when many lots of product have been widely distributed. Seizure, multiple seizure, or other court action is indicated when a firm refuses to undertake a recall requested by the Food and Drug Administration, or where the agency has reason to believe that a recall would not be effective, determines that a recall is ineffective, or discovers that a violation is continuing.

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21 C.F.R. § 7.41(a) provides in part:

Health hazard evaluation and recall classification.

(a) An evaluation of the health hazard presented by a product being recalled or considered for recall will be conducted by an ad hoc committee of Food and Drug Administration scientists and will take into account, but need not be limited to, the following factors:

(1) Whether any disease or injuries have already occurred from the use of the product.

(2) Whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.

(3) Assessment of hazard to various segments of the population, e.g., children, surgical patients, pets, livestock, etc., who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.

(4) Assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed.

(5) Assessment of the likelihood of occurrence of the hazard.

(6) Assessment of the consequences (immediate or long-range) of occurrence of the hazard.

(b) On the basis of this determination, the Food and Drug Administration will assign the recall a classification, i.e., Class I, Class II, or Class III, to indicate the relative

degree of health hazard of the product being recalled or considered for recall.

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21 C.F.R. §§ 7.45(a) provides in part:

Food and Drug Administration-requested recall.

(a) The Commissioner of Food and Drugs or designee may request a firm to initiate a recall when the following determinations have been made:

(1) That a product that has been distributed presents a risk of illness or injury or gross consumer deception.

(2) That the firm has not initiated a recall of the product.

(3) That an agency action is necessary to protect the public health and welfare.

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21 C.F.R. § 7.46(a) provides in part:

Firm-initiated recall.

(a) A firm may decide of its own volition and under any circumstances to remove or correct a distributed product. A firm that does so because it believes the product to be violative is requested to notify immediately the appropriate Food and Drug Administration district office listed in § 5.115 of this chapter. Such removal or correction will be considered a recall only if the Food and Drug Administration regards the product as involving a violation that is subject to legal action, e.g., seizure. . . .

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21 C.F.R. § 803.10(c)(1) provides in part:

Generally, what are the reporting requirements that apply to me?

* * *

(c) If you are a manufacturer, you must submit reports (described in subpart E of this part) to us, as follows:

(1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable death, serious injury, or malfunction.

(2) Submit reports of individual adverse events no later than 5 work days after the day that you become aware of:

(i) A reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health

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21 C.F.R. § 814.3(g) provides in part:

(g) "PMA supplement" means a supplemental application to an approved PMA for approval of a change or modification in a class III medical device, including all information submitted with or incorporated by reference therein.

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21 C.F.R. § 814.47(2) provides in part:

Temporary suspension of approval of a PMA.

(a) Scope. (1) This section describes the procedures that FDA will follow in exercising its authority under section 515(e)(3) of the act (21 U.S.C. 360e(e)(3)). This

authority applies to the original PMA, as well as any PMA supplement(s), for a medical device.

(2) FDA will issue an order temporarily suspending approval of a PMA if FDA determines that there is a reasonable probability that continued distribution of the device would cause serious, adverse health consequences or death.

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21 C.F.R. § 870.3925 provides in part:

Replacement heart valve.

(a) Identification. A replacement heart valve is a device intended to perform the function of any of the heart's natural valves. This device includes valves constructed of prosthetic materials, biologic valves (e.g., porcine valves), or valves constructed of a combination of prosthetic and biologic materials.

(b) Classification. Class III (premarket approval).

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21 C.F.R. § 895.1 provides in part:

(a) This part describes the procedures by which the Commissioner may institute proceedings to make a device intended for human use that presents substantial deception or an unreasonable and substantial risk of illness or injury a banned device.

(b) This part applies to any "device" as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (act) that is intended for human use.

(c) A device that is made a banned device in accordance with this part is adulterated under section 501(g) of the

act. A restricted device that is banned may also be misbranded under section 502(q) of the act.

[LOGO]	DEPARTMENT OF HEALTH & HUMAN SERVICES	Public Health Service Food and Drug Administration

Memorandum

Date Mar. 20, 2000

From Cardiovascular and Neurological Devices Branch, DOEIII Office of Compliance, HFZ-341, CDRH

Subject Recall Number, Health Hazard Evaluation and Recall Strategy; Various Heart Valves and Annuloplasty Rings (see below); St. Jude Medical, St. Paul, MN

To MIN-DO/Dirk J. Mouw/HFR-CE895

We are assigning Recall Nos. Z-454/461-0 to the following subject devices:

Z-454-0 – St. Jude Medical Masters Series Rotatable Aortic Mechanical Heart Valve with Silzone Coating, Cuff type, models:

Standard Polyester: 19AS-601, 21AS-601, 23AS-601, 25AS-601, 29AS-601, 31AS-601.

Expanded Polyester: 19AECS-602, 21AECS-602, 23AECS-602, 25AECS-602, 27AECS-602, 29AECS-602, 31AECS-602.

Hemodynamic Plus cuff: 17AHPS-605, 19AHPS-605, 21AHPS-605, 23AHPS-605, 25AHPS-605, 27AHPS-605.

Expanded HP Cuff: 17AEHPS-605, 19AEHPS-605, 21AEHPS-605, 23AEHPS-605, 25AEHPS-605, 27AEHPS-605.

Z-455-0 – St. Jude Medical Masters Series Rotatable Mitral Mechanical Heart Valve with Silzone Coating, Cuff Type, models:

Standard Expanded Polyester: 19MS-601, 21MS-601, 23MS-601, 25MS-601, 27MS-601, 29MS-601, 31MS-601, 33MS-601, 35MS-601, 37MS-601

Expanded Polyester: 19MECS-605, 19MECS-602, 23MECS-602, 25MECS-602, 27MECS-602, 29MECS-602, 31MECS-602, 33MECS-602.

Hemodynamic Plus: 17MHPS-605, 19MHPS-605, 21MHPS-605, 23MHPS-605 25MHPS-605, 27MHPS-605.

Expanded HP Cuff: 17MEHPS-605, 19MEHPS-605, 21MEHPS-605, 23MEHPS-605, 25MEHPS-605, 27MEPHS-605.

Z-456-0 – St. Jude Medical Regent Rotatable Aortic Mechanical Heart Valve with Standard Polyester Cuff Having Silzone Coating, models: 17-AG-701, 19-AG-701, 21-AG-701, 23-AG-701, 25-AG-701, 27-AG-701, 29-AG-701;

Z-457-0 – St. Jude Medical Regent Rotatable Aortic Mechanical Heart Valve with Flex/ Polyester Cuff Having Silzone Coating, models: 17AGF706, 19AGF706, 21AGF706, 23AGF706, 25AGF706, 27AGF706, 29AGF706;

Z-458-0 – St. Jude Medical Seguin Annuloplasty Ring for Mitral Valve Repair with Silzone Coating, models: SARS-M24, SARS-M26, SARS-M28, SARS-M30, SARS-M32, SARS-M34, SARS-M36, SARS-M38, SARS-M40;

Z-459-0 – St. Jude Medical Tailor Annuloplasty Ring with Silzone Coating, models: TAR-25, TAR-27, TAR-29, TAR-31, TAR-33, TAR-35;

Z-460-0 – St. Jude Medical Epic Porcine Aortic Bioprosthetic Heart Valve, models: ELS-21A, ELS-23A, ELS-25A, ELS-27A, ELS-29A, ELS-31A;

Z-461-0 – St. Jude Medical Epic Porcine Mitral Bioprosthetic Heart Valve, models: ELS-21M, ELS-23M, ELS-25M, ELS-27M, ELS-29M, ELS-31M

We are classifying the firm's action as a voluntary recall. We consider the devices to be adulterated and misbranded because there is a statistically significant higher rate of paravalvular leaks with the silver ion (Silzone) coated sewing cuffs leading to valve explants. The device defect presents a moderate risk of adverse health consequences.

Recall Strategy:

(1) Class: II

(2) Depth: Medical Facilities and Physicians

(3) Firm Effectiveness Check: Level C – Firm is to conduct effectiveness checks on 10% of all final users.

(4) FDA Audit Check: Level E – LOS-DO is to review firm's records to determine effectiveness.

(5) Publicity: FDA Enforcement Report only.

CDRH suggests that you telephone the firm immediately to inform them of the recall numbers and strategy and that this information will be published in the FDA Enforcement Report. For ongoing recalls, please advise the firm that CDRH expects all recall related activity to be

completed within six months and final status report submitted to the district office for termination by FDA.

/s/ Mary Ann Fitzgerald
Mary Ann Fitzgerald
(301) 594-4648, Ext. 130

DEPARTMENT OF HEALTH & HUMAN SERVICES

[Address Omitted In Printing]

March 22, 2000

Mr. Terry L. Shepherd
President and Chief Executive Officer
St. Jude Medical, Inc. RE: Recall Numbers Z-454/461-0
One Lillehei Plaza
St. Paul, MN 55117

Dear Mr. Shepherd:

We agree with your firm's decision to recall:

28 models of SJM Masters Series Rotatable Aortic Mechanical Heart Valves with Silzone Coating,

28 models of SJM Masters Series Rotatable Mitral Mechanical Heart Valves with Silzone Coating,

7 models of SJM Regent Rotatable Aortic Mechanical Heart Valves, with Standard Polyester Cuff having Silzone Coating,

7 models of SJM Regent Rotatable Aortic Mechanical Heart Valves, with Flex/Polyester Cuff having Silzone Coating,

9 models of SJM Seguin Annuloplasty Rings with Silzone Coating,

6 models of SJM Tailor Annuloplasty Rings with Silzone Coating,

6 models of SJM Epic Porcine Aortic Bioprosthetic Heart Valves, and

6 models of SJM Epic Porcine Mitral Bioprosthetic Heart Valves.

The use of the mechanical heart valves having cuffs with Silzone Coating has been associated with a statistically-significant higher rate of paravalvular leaks, and with a significantly-higher rate of explant due to endocarditis.

We have reviewed your action and conclude that it meets the formal definition of a "Recall". This is significant, as your action is an alternative to a Food and Drug Administration legal action to remove the defective products from the market. This recall will be reported in an upcoming issue of the "FDA Weekly Enforcement Report".

It is suggested that, in conducting your recall, you follow the FDA's "Enforcement Policy – Recalls (including Product Corrections) – Guidelines on Policy, Procedures and Industry Responsibilities," issued June 16, 1978. Enclosed you will find a copy of this "Enforcement Policy," as well as a copy of the FDA's "Methods for Conducting Recall Effectiveness Checks".

This recall has been classified by the FDA as a Class II recall. This means that the recall involves a situation in which the use of the violative products may cause temporary or medically-reversible adverse health consequences, or where the probability of serious adverse health consequences is remote.

Our evaluation indicates that this recall should be conducted to the physician level, and that level C effectiveness checks should be conducted by your firm. Level C effectiveness checks, in this case, means following up with 10% of your consignees to determine if they understood and followed your instructions.

In addition to your recall efforts, it is equally important to assure that all returned merchandise is promptly inventoried,

handled, and stored in such a manner as to assure its separation from acceptable materials so it will not inadvertently be used or shipped. Our past experience in similar situations has shown that the longer a defective product is held between the initiation and termination of a recall, the greater the chance of its accidental misuse. We, therefore, urge you to immediately begin making plans to destroy the product or recondition it to bring it into compliance with the law.

We request that you advise us within ten days of the steps you have taken or will take to ensure that the recalled merchandise is properly inventoried and maintained to prevent unintended use or shipment, and provide your proposed method of disposition of the returned goods.

In addition, we request that you submit a recall status report to our Minneapolis District Office at monthly intervals, beginning with the month of April. These recall status reports should reach the Minneapolis District Office before the 25th of each month. If you have completed your recall actions at this time, you will only need to send one summary report. The recall status reports should contain the following information:

1. Number of consignees notified of the recall, and date and method of notification.
2. The number of consignees responding to the recall communication, and the amount of product on hand at the consignees at the time the communication was received.
3. Number of consignees that did not respond.

4. The amount of the products returned or destroyed by the consignees contacted, and the quantity of the products accounted for.
5. The number and results of effectiveness checks that were made.
6. The estimated time frame for completion of the recall or when the recall was completed.
7. Amount of the products on hand at your firm when the recall began, and the disposition of these products.
8. Actions taken to prevent recurrence of the problem.
9. Number and summary of any complaints received about the problem since the recall began.

These periodic recall status reports should be addressed to Dirk J. Mouw, Recall and Emergency Coordinator at the Minneapolis District Office, Information indicated as needed in items 7-9 is for closing the recall, and need only be supplied in your final report.

Our judgment regarding the effectiveness of the recall will largely be based upon your implementation of the enclosed recall guidelines. Please be advised that failure to conduct an effective recall could result in seizure of the violative product in commerce or other legal sanctions under the Food, Drug & Cosmetic Act.

Your response to this letter should be addressed to James A. Rahto, District Director.

Your cooperation in this matter is obviously important for the protection of the general public.

Sincerely,

/s/ Edwin S. Dee
Edwin S. Dee
Acting Director,
Minneapolis District

Enclosures

cc: Donald S. Guzik
Vice President, Quality Systems
St. Jude Medical, Inc.
One Lillehei Plaza
St. Paul, MN 55117

2004 WL 45503

IN RE: ST. JUDE MEDICAL, INC. SILZONE HEART VALVES PRODUCTS LIABILITY LITIGATION

MDL No. 01-1396 (JRT/FLN)

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MINNESOTA

2004 U.S. Dist. LEXIS 148

January 5, 2004, Decided

COUNSEL: J. Gordon Rudd, Jr. and Charles S. Zimmerman, ZIMMERMAN REED, P.L.L.P., Minneapolis, MN; Steven E. Angstreich, Michael Coren, and Carolyn Lindheim, LEVY, ANGSTREICH, FINNEY, BALDANTE, RUBENSTEIN & COREN, P.C., Woodcrest Pavilion, Cherry Hill, NJ; James T. Capretz, CAPRETZ & ASSOC., Newport Beach, CA; Joe D. Jacobson, GREEN, SCHAAF & JACOBSON, P.C., St. Louis, MO; and Patrick Murphy, BOCHANIS AND MURPHY LEGAL ASSOCIATES, Las Vegas, NV, for plaintiffs.

Tracy J. Van Steenburgh, HALLELAND, LEWIS, NILAN, SIPKINS & JOHNSON, Minneapolis, MN; James C. Martin and David E. Stanley, REED SMITH CROSBY HEAFEY LLP, Los Angeles, CA; Steven M. Kohn, REED SMITH CROSBY HEAFEY LLP, Oakland, CA, for defendant.

JUDGES: JOHN R. TUNHEIM, United States District Judge.

OPINION BY: JOHN R. TUNHEIM

OPINION:

MEMORANDUM OPINION AND ORDER DENYING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

On April 18, 2001, the cases making up this multidistrict litigation were transferred to this Court by the Judicial Panel on Multidistrict Litigation for consolidated pretrial proceedings under 28 U.S.C. § 1407. Defendant St. Jude Medical ("St. Jude" or "SJM") requests summary judgment, arguing that all plaintiffs' claims are preempted by federal law. Plaintiffs argue that key material fact questions prevent summary judgment. The motion was extensively briefed, and the Court heard lengthy argument on the matter. For the reasons discussed below, defendant's motion is denied.

BACKGROUND

I. Factual Background[1]

Defendant St. Jude, a company with headquarters and manufacturing facilities in Minnesota, manufactures a variety of medical devices including prosthetic heart valves. Such valves are surgically implanted into patients whose natural valves have been damaged by disease. Among St. Jude's products is the Silzone heart valve, which has a coating of silver on the sewing cuff, the part of the valve that is sewn to the patient's body. Aside from the

[1] In support of their respective positions, both parties submitted multi-volume Appendices. For ease of reference, the Court will cite to these Appendices as, for example, "Pl.App. Vol. X at Tab. Y." In addition, defendant submitted two affidavits not in Appendix form. Those will be referred to by the last name of the affiant, and the Tab (exhibit) number. Finally, the Court also cites to the parties' respective memoranda as "Def. Brief" or "Def. Reply" and "Pl. Brief."

silver coating, the Silzone valve is essentially the same as other St. Jude heart valves that have been approved by the U.S. Food and Drug Administration ("FDA") since 1995. Silver has been known to have anti-microbial properties, and St. Jude introduced the silver-coated valves to combat endocarditis, a potentially life-threatening infection of the cardiac tissue that is a well-known possible consequence of prosthetic heart valve implantation.

The FDA approved the Silzone valve for commercial distribution on March 24, 1998. As part of this approval, however, the FDA prohibited St. Jude from claiming that the Silzone coating would reduce the risk of endocarditis, as no clinical tests had been performed to study this claim.[2] After the FDA approved the Silzone valve, St. Jude sponsored the Artificial Valve Endocarditis Reduction Trial ("AVERT") study, a multinational clinical trial designed to study whether the Silzone-coated heart valve reduced the incidence of endocarditis in humans. Approximately 36,000 Silzone valves have been implanted in patients worldwide, with approximately 10,535 of these in the United States. AVERT was originally intended to involve 4,400 heart valve patients. However, the study enrolled only 792 patients, with approximately half of those receiving Silzone-coated valves and another half, the control group, receiving conventional (non-Silzone) valves. The results of AVERT are reviewed by an independent monitoring board.

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[2] The FDA also required that all labels bearing the name "Silzone" must carry the following statement: "No clinical studies have been performed to evaluate the effect of the Silzone coating in reducing the incidence of endocarditis."

In January 2000, the AVERT monitoring board reported that recipients of the Silzone valve were more likely than recipients of conventional valves to experience a complication called paravalvular leak,[3] requiring the prosthetic valve to be removed and replaced with another valve. The data showed that two percent of AVERT participants with Silzone valves required such an "explant," while only .25 percent of participants with conventional valves required the procedure. On January 21, 2000, the monitoring board decided to suspend enrollment in the AVERT trial because of this increase in paravalvular leak.[4] On the same day, St. Jude voluntarily recalled all unimplanted Silzone products. As part of the recall, St. Jude notified hospitals and physicians, instructing them not to use Silzone products. St. Jude also sent letters regarding the care and management of patients with implanted Silzone valves, and established a reimbursement program to pay for uninsured medical costs associated with the detection, diagnosis and treatment of paravalvular leak.

In response to the voluntary recall, the FDA informed St. Jude that its actions would be considered a "recall." *See* Plaintiffs' Appendix Vol. VI, Ex. 100, March 20, 2000, Memorandum from Cardiovascular and Neurological Devices Branch ("We are assigning recall numbers to [Silzone valves] . . . We are classifying the firm's actions as a voluntary recall."). *See also* Plaintiffs' Appendix Vol. V, Ex. 24, March 22, 2000 letter from Edwin Dee to St. Jude

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[3] Paravalvular leak involves leakage at the point where a heart valve is sutured to a patient's tissue. *See* J.E. Schmidt, *Attorney's Dictionary of Medicine and Word Finder*, Vol. 4, P-79 (2002).

[4] Although enrollment in AVERT was suspended, the participants continue to be monitored and data are still collected and studied.

("We agree with your firm's decision to recall [the Silzone valve] . . . We have reviewed your action and conclude that it meets the formal definition of a 'Recall'. This is significant, as your action is an alternative to a Food and Drug Administration legal action to remove the defective products from the market.").

II. Statutory Regulatory Scheme

Regulation of medical devices is governed by the Federal Food, Drug, and Cosmetic Act (FDCA), 52 Stat. 1040, as amended by the Medical Device Amendments of 1976(MDA), 90 Stat. 539, 21 U.S.C. § 301. *See generally Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344, 148 L. Ed. 2d 854, 121 S. Ct. 1012 (2001). Devices are separated into three Classes (I, II, and III). The Silzone valve is a Class III device. Class III devices are defined as those devices that "present a potential unreasonable risk of illness or injury." § 360c(a)(c)(ii)(II). Because of the potential risks, Class III devices are subject to the strictest regulation of the three classes of devices. *Id.*

Typically, Class III devices must undergo an exhaustive review process with the FDA, called premarket approval (PMA) before they may be approved and marketed. The PMA "requires the applicant to demonstrate a 'reasonable assurance' that the device is both 'safe . . . [and] effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.'" *Buckman*, 531 U.S. at 344 (quoting §§ 360e(d)(2)(A), (B)).

There are also "exemptions" to the PMA process, one such exemption is the 510k exemption. The 510k process allows devices that are "substantially equivalent" to

medical devices in existence in 1976 to be marketed and sold without PMA approval, in order not to stifle competition with technology existing at the time of the enactment of the MDA. *See* 21 U.S.C. § 360j(g)(1). This limited form of review "averages only 20 hours of review as opposed to some 1200 hours in the PMA process." *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 221-22 (6th Cir. 2000) (herinafter "*Kemp*") (citing *Martin v. Telectronics Pacing Sys.*, 105 F.3d 1090, 1095 (6th Cir. 1997); *Reeves v. AcroMed Corp.*, 103 F.3d 442, 446 (5th Cir. 1997)).[5]

If the FDA approves a PMA, "it does so subject to conditions described in a document entitled 'Conditions of Approval.'" *Kemp*, 231 F.3d at 223. The Conditions of Approval form "requires manufacturers to submit the device's proposed labeling before marketing, limits advertising to the approved labeling, requires the manufacturer to submit a PMA supplement for review and approval before making any change affecting the safety or effectiveness of the device, requires the manufacturer to submit post-approval reports, and requires the manufacturer to report any incidents of adverse reaction to, or known defect of, the approved device." *Woods v. Gliatech, Inc.*, 218 F. Supp. 2d 802, 805-06 (W.D. Va. 2002).

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[5] There is also an exemption for experimental or investigational devices (investigational device exemption or "IDE"). The IDE provides an exemption for devices representing innovative technology, and allows for unapproved devices to be utilized in human trials. An IDE permits a manufacturer to market "a device that otherwise would be required to comply with a performance standard or to have premarket approval for the purpose of conducting investigations of that device." 21 C.F.R. § 812.1.

FDA regulations provide that:

> FDA may impose postapproval requirements in a PMA approval order . . . Postapproval requirements may include as a condition to approval of the device: . . . (2) continuing evaluation and periodic reporting on the safety, effectiveness, and reliability of the device for its intended use. FDA will state in the PMA approval order the reason or purpose for such requirement and the number of patients to be evaluated and the reports required to be submitted . . . (9) Such other requirements as FDA determines are necessary to provide reasonable assurance, or continued reasonable assurance, of the safety and effectiveness of the device.

21 C.F.R. § 814.82(a). "A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80.

The FDA can withdraw approval if the manufacturer has not met all post-approval requirements, if the device is unsafe or ineffective, or if the PMA contained or was accompanied by an untrue statement of material fact. 21 U.S.C. § 360(e)(1) and 21 C.F.R. 814.46. At least one court has held that the failure to comply with PMA conditions invalidates FDA approval. *Woods,* 218 F. Supp. 2d at 808 n.4.

III. Approval of the Silzone Valve

The Silzone valve was a modification to St. Jude's previously approved heart valve, as such, the Silzone valve itself did not go through the PMA process, but instead was

approved via the "PMA Supplement" process.[6] 21 U.S.C. § 360e(d)(6)(A)(i); 21 C.F.R. § 814.39. *See Kemp v. Medtronic, Inc.*, 231 F.3d 216, 221-22 (6th Cir. 2000) ("Should a manufacturer merely propose to modify a Class III device that has already received approval pursuant to the PMA process, the manufacturer may submit a PMA Supplement rather than re-submitting the entire device for review.") *See generally United States v. Prigmore*, 243 F.3d 1, 5 (1st Cir. 2001) (describing PMA supplement process). The PMA Supplement, like the initial PMA application "must contain scientific information that provides a basis for approval of the modified device." *Prigmore*, 243 F.3d at 5 (quoting 21 C.F.R. § 814.39(c)). *Id.* "All procedures and actions that apply to [a PMA] application under § 814.20 also apply to PMA supplements." § 814.39(c).

Defendant argues that approval pursuant to a PMA supplement is "sufficient evidence" that the device is "reasonably safe and effective for its intended use," and that therefore any claims based on the safety or efficacy of the device must be preempted. (Def. Brief at 17.) Defendant has submitted volumes of exhibits in support of its argument that the FDA carefully considered the approval, and that the PMA Supplement was exhaustive. For example, defendant submits exhibits indicating that St. Jude provided at least five "addendums" to the PMA Supplement. Each supplement addressed specific concerns voiced by FDA officials or consultants.

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[6] The previously approved valve was the "Masters Series" valve, which itself was approved via a PMA supplement, rather than the full-blown PMA process.

Despite this evidence, plaintiffs assert that FDA approval was improperly secured and unlawfully maintained. In support of this argument, plaintiffs submit the affidavits of three experts.[7] The gist of those affidavits is that St. Jude concealed information from the FDA, and that had that information been made available, the FDA would not have approved the valve. Plaintiffs suggest that because their claims are premised on the contention that St. Jude failed to comply with FDA regulations, there is no preemption. *See Brooks,* 273 F.3d at 798 ("a claim of failure to comply with FDA regulations is not preempted by the MDA, since such a state claim imposes no requirements different from, or in addition to any federal requirement") (internal quotation and citations omitted).

Plaintiffs also argue that although the approval was ostensibly PMA approval, in reality the FDA used a 510k-type approval (the much less intensive approval described above). The 510k process was at issue in *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 135 L. Ed. 2d 700, 116 S. Ct. 2240 (1996) (herinafter "*Lohr*") a case in which the Supreme Court determined that plaintiff's claims were not preempted. Citing *Lohr,* plaintiffs argue that because 510k approval is based on equivalence, not safety, their claims are not preempted. Finally, plaintiffs alternatively argue that the express preemption of 360k(a) cannot apply, because the device approved is actually a drug or drug/device combination, not a device. The distinction between drug and device, plaintiffs argue, is one for the Court. Plaintiffs suggest that the FDA never determined that the Silzone valve was a device, rather than a

[7] These affidavits are the subject of a motion to strike, which is addressed below.

drug/device combination. Even if the FDA made such a determination, plaintiffs continue, this Court owes no deference to it because Congress, and not the FDA, divided medical implements into categories of either drug or device.

ANALYSIS

I. Standard of Review

Rule 56(c) of the Federal Rules of Civil Procedure provides that summary judgment "shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56. Only disputes over facts that might affect the outcome of the suit under the governing substantive law will properly preclude the entry of summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986). Summary judgment is not appropriate if the dispute about a material fact is genuine, that is, if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. *Id.* Summary judgment is to be granted only where the evidence is such that no reasonable jury could return a verdict for the nonmoving party. *Id.*

The moving party bears the burden of bringing forward sufficient evidence to establish that there are no genuine issues of material fact and that the movant is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (1986). The nonmoving party is entitled to the benefit

of all reasonable inferences to be drawn from the underlying facts in the record. *Vette Co. v. Aetna Casualty & Surety Co.*, 612 F.2d 1076, 1077 (8th Cir. 1980). However, the nonmoving party may not merely rest upon allegations or denials in its pleadings, but it must set forth specific facts by affidavits or otherwise showing that there is a genuine issue for trial. *Forrest v. Kraft Foods, Inc.*, 285 F.3d 688, 691 (8th Cir. 2002).

II. Preemption Principles

The Supremacy Clause of the United States Constitution provides that the "Laws of the United States . . . shall be the supreme Law of the Land." U.S. Const. art. VI, cl. 2. The principle of preemption is the application of this clause, resulting in the rule that any "state law that conflicts with federal law is 'without effect.'" *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516, 120 L. Ed. 2d 407, 112 S. Ct. 2608 (1992). Preemption is disfavored in areas of historic importance to the states' police powers – areas such as public health and safety. *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 222 (6th Cir. 2000). *See also Buckman Co. v. Plaintiffs' Legal Committee,* 531 U.S. 341, 148 L. Ed. 2d 854, 121 S. Ct. 1012 (2001) (no presumption against preemption where plaintiffs' claims involved medical devices, but were more accurately characterized as "fraud on the FDA" claims because "policing fraud against federal agencies is hardly a field which the States have traditionally occupied") (internal quotation omitted).

Preemption is typically understood as having two types – express and implied. Express preemption is found when Congress "pre-empt[s] state law by so stating in express terms." *Hillsborough County, Fla. v. Automated*

Med. Labs, Inc., 471 U.S. 707, 712-13, 85 L. Ed. 2d 714, 105 S. Ct. 2371 (1985) (citing *Jones v. Rath Packing Co.*, 430 U.S. 519, 525, 51 L. Ed. 2d 604, 97 S. Ct. 1305). Implied preemption, in turn, has two types – field preemption, and conflict preemption. Field preemption occurs when Congress legislates so pervasively in a particular field that no room remains for concurrent state legislation. *Id.* Conflict preemption occurs

> even where Congress has not completely displaced state regulation in a specific area, state law is nullified to the extent that it actually conflicts with federal law. Such a conflict arises when compliance with both federal and state regulations is a physical impossibility, or when state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

Id. (internal quotations omitted).

"Central to determining questions of preemption is divining Congress' intent." *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 222 (6th Cir. 2000) (citing *Cipollone*, 505 U.S. at 517-18). Courts must be careful to avoid the "unintended encroachment on the authority of the States" and therefore "will be reluctant to find pre-emption" where the subject is one "traditionally governed by state law." *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 663-64, 123 L. Ed. 2d 387, 113 S. Ct. 1732 (1993). Where Congress has included an express preemption provision in a statute, courts historically have not looked beyond it to consider implied preemption. *Kemp*, 231 F.3d at 222. However, since *Buckman Co. v. Plaintiff's Legal Comm.*, it is clear that express and implied preemption are not mutually

exclusive. Therefore, the Court discusses both express and implied preemption.

A. Express Preemption – *Section 360k*

At issue in these cases is the express preemption provision of the MDA, which states:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any **requirement** – (1) which is different from, or in addition to, any **requirement** applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (emphasis added).

1. What is a "requirement"

Courts have struggled to divine Congress's intent in § 360k – specifically, courts have differed in the understanding of what was meant by the term "requirement" in the context of a "requirement" imposed by a State (or political subdivision). Some courts have reasoned that "requirement" is intended to encompass only State legislative, statutory "requirements." *See Oja v. Howemedica, Inc.*, 111 F.3d 782, 789 (10th Cir. 1997) (interpreting *Lohr* and holding that "requirement" meant only state statutory requirements). Others determined that the term "requirements" was intended to include common-law tort claims as well. *See, e.g., Martin*, 254 F.3d at 579-83; *Kemp*, 213 F.3d at 224.

These differing understandings stem from the Supreme Court's discussion of "requirements" in *Lohr*. Justice Stevens, writing for a plurality, rejected as "implausible" the medical device manufacturer's suggestion that "any common-law cause of action is a 'requirement' which alters incentives or imposes duties 'different from, or in addition to,' the generic federal standards." *Lohr*, 518 U.S. at 486-87. Justice Stevens discussed the language of § 360k, the legislative history, and the fact that members of both houses "were acutely aware of ongoing product liability litigation" when the section was enacted. *Id.* at 487-491. Stevens concluded that § 360k "simply was not intended to preempt most, let alone all general common-law duties enforced by damages actions." *Id.* at 491. Despite this discussion, Stevens did not "respond directly" to the plaintiff's contention that common-law duties are **never** requirements within the meaning of § 360k and that the statute therefore never pre-empts common-law actions. *Id.* at 502-03.

Justice Bryer, writing separately, noted that "[o]ne can reasonably read the word 'requirement' as including the legal requirements that grow out of the application, in particular circumstances, of a State's tort law." *Id.* at 504. Bryer used the example of a federal regulation of hearing aids requiring a two-inch wire, and a state regulation requiring a one-inch wire. The state regulation would clearly be pre-empted, Bryer reasoned, therefore a jury award of damages based on the one-inch wire would also be pre-empted. *Id.*

The Supreme Court has revisited its holding in *Lohr* to insinuate that the term "requirement" in the MDA applies to tort claims as well as particular state statutory "requirements." *See Geier v. American Honda Motor Corp.*,

529 U.S. 861, 867, 146 L. Ed. 2d 914, 120 S. Ct. 1913 (2000) ("a majority of this Court has said that . . . a provision that uses the word 'requirements' – **may** well expressly pre-empt similar tort actions."). (Emphasis added) (citing *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 502-04, 135 L. Ed. 2d 700, 116 S. Ct. 2240 (1996) (plurality opinion); *id.* at 503-05 (Breyer, J. concurring in part and concurring in judgment); *id.,* at 509 – 12 (O'Connor, J. concurring in part and dissenting in part)); *American Honda Motor Corp.,* 529 U.S. 861, 897, 146 L. Ed. 2d 914, 120 S. Ct. 1913 (2000) (Stevens, J. dissenting) ("And in *Medtronic v. Lohr,* we recognized that the statutory reference to 'any requirement' imposed by a State or its political subdivisions **may** include common-law duties.") (citations omitted) (emphasis added). Despite this language, there has been no explicit holding by the Supreme Court, in the medical device realm, that any particular common law claim has constituted a "requirement ."

Equally difficult has been determining what constitutes the federal requirement. At least two approaches have been put forth. Some courts have applied a process-oriented definition to the term "requirement." *See, e.g., Mitchell v. Collagen Corp.,* 126 F.3d 902 (7th Cir. 1997). Those courts reason that the PMA process itself, without more, constitutes the "requirement" mentioned in the statute. Another approach is to look at the device specific edicts from the FDA, and consider those edicts the "requirements" of 360k.

Some Courts have held that the PMA process itself is a federal "requirement" imposed by the MDA. *See Mitchell,* 126 F.3d 902 (holding that unlike the 510k process, the PMA process can constitute the sort of specific federal "requirement" that can have preemptive effect

under the MDA); *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001) (same). There is a division of authority, however, and the Eleventh Circuit has reached the opposite conclusion. *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir.) *reh'g* and *reh'g en banc* denied (1999) (holding that the PMA process itself is not a "requirement" and reasoning that the ordinary construction of the language of 360k and use of the term "requirement" in the broader statutory context and the FDA regulations contemplate the imposition of some identifiable precondition that applies to the device in question); *Woods v. Gliatech, Inc.*, 218 F. Supp. 2d 802 (W.D. Va. 2002) (holding that PMA approval represents only a finding that the device manufacturer has reasonably assured the FDA of the safety and effectiveness, and also finding that PMA approval **does not** provide any indication of what, if any, specific substantive requirements the FDA may have applied to reach that result); *Webster v. Pacesetter, Inc.*, 171 F. Supp. 2d 1, 9 (D.D.C. 2001) (rejecting argument that PMA process amounts to a "requirement"); *Quillin v. American Hosp. Supply Co.*, 1997 U.S. Dist. LEXIS 6974, 1997 WL 382095 (N.D. Okl., March 31, 1997) (PMA process does not constitute a "requirement" for the purpose of determining whether a plaintiff's state common law claims are preempted). The Supreme Court has not addressed the issue.

Prior to *Lohr*, the Eighth Circuit had held that the PMA process itself constituted a "requirement." *See Martello v. Ciba Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994). However, in *Brooks v. Howmedica*, the Eighth Circuit, sitting *en banc*, retreated from that broad holding. *See Brooks v. Howmedica*, 273 F.3d 785, 795 (8th Cir. 2001), *cert. denied*, 535 U.S. 1056, 152 L. Ed. 2d 823, 122 S. Ct. 1914 (2002) (noting that the *Martello* holding "requires

some modification" to be consistent with the Supreme Court's decision in *Lohr*). The *Brooks* Court did not hold that the PMA process itself amounts to a requirement. Instead, the *Brooks* Court carefully compared the plaintiff's claims with the federal requirements and determined that "the failure to warn claim [plaintiff] Brooks seeks to assert could impose state requirements which conflict or interfere with these federal directives. Because these 'particular state requirement[s] threaten[ ] to interfere with . . . specific federal interest[s],' *Lohr,* 518 U.S. at 500, 116 S. Ct. 2240, Brooks' claim is preempted by the MDA." *Id.* at 798 (alteration and internal quotation in original).

B. Applying express preemption

1. *Medtronic, Inc. v. Lohr*

In *Medtronic, Inc. v. Lohr,* the Supreme Court first discussed whether the MDA preempts particular common law tort claims. 518 U.S. 470, 135 L. Ed. 2d 700, 116 S. Ct. 2240 (1996). The plaintiff in *Lohr* had received a pacemaker (a Class III device) that had been approved under the 510k process. Plaintiff asserted claims of negligence and strict liability against the manufacturer, alleging defendant had failed to use reasonable care during production. The Court, in a plurality opinion, held that none of plaintiff's claims were preempted. Specifically, the Court held that the MDA does not preempt state or local requirements that are equal to, or substantially identical to, requirements imposed under federal law. Similarly, the Court held that plaintiff's claims were not preempted to the extent that they alleged that the manufacturer failed to comply with duties equal to, or substantially identical to, federal requirements.

In response to the defendant's preemption argument, the *Lohr* Court emphasized that it would be "to say the least, 'difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct,' and it would take language much plainer than the text of § 360k to convince us that Congress intended that result." *Id.* at 484 (quoting *Silkwood v. Kerr-McGee Corp.,* 464 U.S. 238, 251, 78 L. Ed. 2d 443, 104 S. Ct. 615 (1984)). The Court went on to note that, "[n]othing in 360k denies [States] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Id.* at 495.

Lohr generated confusion as the circuit courts attempted to discern its specific holding, and apply it in subsequent cases, including cases in which plaintiffs were injured by devices that had been approved through the full PMA process, and cases in which plaintiffs pled alternate theories of liability. *See Kemp,* 231 F.3d at 221 (noting that "Courts of appeals that have confronted the issues of preemption arising under the MDA have struggled mightily with *Lohr's* language in the effort to discern its holding" and further noting that "this appeal presents fractious issues which have sharply divided the various circuit courts which have considered them."). *Compare Kemp,* 231 F.3d 216 (granting summary judgment to pacemaker manufacturer on preemption grounds) *with Goodlin v. Medtronic, Inc.,* 167 F.3d 1367 (11th Cir. 1999) (facts and legal theories almost indistinguishable, but refusing to find plaintiff's claims preempted).

2. *Brooks v. Howmedica*

In *Brooks v. Howmedica,* 273 F.3d 785 (8th Cir. 2001), *cert. denied,* 535 U.S. 1056, 152 L. Ed. 2d 823, 122 S. Ct. 1914 (2002), the Eighth Circuit, sitting *en banc,* reversed its panel decision, and denied relief to a former orthopedic surgical nurse who had been injured by repeated on-the-job exposure to toxins released as she mixed bone cement.[8] The *Brooks* court held that plaintiff's claims of negligent failure to warn and failure to comply with federal labeling regulations were expressly preempted.[9] In reaching this conclusion, the court discussed the extensive regulation to which defendant was subject, and noted that the approval process "included review by the FDA of the proposed design and content for all Simplex labels" and that "the FDA drafted the language that was used in the package insert." The court also emphasized that the case involved "ascertainable requirements" taking the form of "a series of mandates regarding the label" issued by the FDA. Under the *Brooks* analysis, such mandates amount to the federal "requirement" with which state "requirements" must not conflict.

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[8] It is noteworthy that the plaintiff in *Brooks* was in a different position than the typical plaintiff – that is, plaintiff Brooks was not a recipient of the medical device at issue, rather, her injuries were caused by mixing the bone cement to prepare the device for surgery.

[9] The Eighth Circuit mimicked the Supreme Court in declining to address the "other" preemption category – that is, the Supreme Court in *Buckman* stated in a footnote that because it found plaintiffs' claims impliedly preempted, it would not address express preemption. In *Brooks* the Eighth Circuit, also in a footnote, noted that "because we find express preemption, we do not address any potential issue of implied preemption." *Id.* at 792 n.7.

The *Brooks* court articulated a "three-step test" to determine if a plaintiff's state law claim is preempted – first, discern the federal requirement imposed on a medical device manufacturer; next, determine the state requirement; finally compare the two to see if there is conflict. *Id.* at 794 ("*Lohr* instructs that state requirements – including common law duties – are preempted **to the extent that they interfere with specific federal requirements.** The state and federal restrictions must be 'carefully compared' to ascertain whether there is interference between them – that being the 'overarching concern' of the test articulated by Justice Stevens and joined in by Justice Breyer.") (emphasis added) (quoting *Lohr,* 518 U.S. at 500).

C. Implied preemption – *Buckman Co. v. Plaintiffs' Legal Committee*

After *Lohr,* the Supreme Court next examined the issue of preemption in the MDA context in *Buckman Co. v. Plaintiffs' Legal Comm.,* 531 U.S. 341, 148 L. Ed. 2d 854, 121 S. Ct. 1012 (2001). In *Buckman,* plaintiffs injured by orthopedic bone screws brought suit alleging that defendant, a regulatory consultant, had made fraudulent representations to the FDA in order to obtain approval to market the devices. The *Buckman* Court declined to address whether express preemption applied, holding that plaintiffs' "fraud on the FDA" claims were **impliedly** preempted. The Court noted that the FDA itself is charged with policing fraud on it and has a variety of enforcement options that allow it to make "a measured response to suspected fraud." *Id.* at 350. Therefore, the state fraud on the FDA claims conflicted with the FDCA – specifically, permitting plaintiffs' claims would conflict with the FDA's

responsibility to police fraud consistently with its judgment and objectives.

In *Buckman,* despite the express preemption provision of 360(k) the Court found implied preemption applicable. In doing so, the Court did not clarify the confusion surrounding the appropriate use of implied versus express preemption. In fact, the Court specifically "expressed no view on whether the[] claims [were] subject to express pre-emption under 21 U.S.C. § 360k." *Id.* at 348 n.2. The failure to address whether both types of preemption could apply is significant, because, until *Buckman,* an oft-cited rule was that where express preemption applied, courts would not use the implied preemption theory. *See Cipollone v. Liggett Group, Inc.,* 505 U.S. 504, 517, 120 L. Ed. 2d 407, 112 S. Ct. 2608 (1992) ("Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted.") (citations omitted). The *Buckman* Court also chose not to specify whether preemption analysis differs depending on the process through which the at-issue devices was approved (510k, PMA, or IDE).

Though instructive,[10] *Buckman* is distinguishable on several important grounds. First, the device approved in *Buckman* was approved via the 510k process, not the PMA/PMA Supplement process. In addition, the bone

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[10] Defendant, while distinguishing a case from the Tenth Circuit, suggests that where a different method of approval is at issue (such as the 510k approval), the case "does not inform the issues before this Court." (Def. Brief at 10 n.5.) The Court disagrees with this characterization, and finds useful those cases that involve other types of FDA approval, including *Buckman* and *Oja v. Howmedica, Inc.,* 111 F.3d 782, 789 (10th Cir. 1997).

screws at issue in *Buckman* were being used "off-label" (they were approved for use in long bones, but were being used in back surgeries), an important distinction because Congress has repeatedly and explicitly noted that the FDA is not designed to interfere with practice of medicine. Plaintiffs in *Buckman* made only "fraud on the FDA claims." The Court specifically noted that states do not have a traditional interest in policing fraud on government agencies. The Court also emphasized that the MDA set up a comprehensive scheme for policing fraud, and that consumers could petition the FDA to take action against suspected wrongdoing. The harm complained of in *Buckman* was the fraud itself, as allegedly perpetrated by the consulting group, not the plaintiffs' personal injuries. In fact, the manufacturer of the bone screws had settled with plaintiffs before the case was appealed to the Supreme Court. *See* Daniel W. Sigelman, *Is Fraud-on-the-FDA a Dead Letter After Buckman v. Plaintiffs' Legal Committee?*, 2 ATLA-CLE 2483 (2001) (noting that AcroMed Corporation, maker of the devices at issue, settled after Third Circuit's opinion). The remaining defendant was an FDA consultant who was not responsible for the design of the device, only for the manner in which the application was presented to the FDA.

III. Discerning the Federal "Requirements"

The parties understandably dispute the fundamental issue of what constitutes "requirements" of federal law in this case. This dispute is predictable, given the conflicting authority in both federal and state courts, as discussed above. The Court notes theoretical and practical difficulties in the "process" approach. Accepting the "process" argument – that the PMA Supplement process itself is a

requirement – makes it difficult as a practical matter to find any claim that is not preempted. On a more theoretical level, this broad immunity is not consistent with Congressional intent in enacting the MDA, *see generally Lohr,* 518 U.S. at 490-92 (discussing congressional history), and is also not consistent with the presumption against preemption in areas of traditional state control (such as health and safety). *See id.* at 475 ("Throughout our history the several States have exercised their police powers to protect the health and safety of their citizens."). Despite these shortcomings to the process approach, a majority of federal courts have held that the PMA/PMA Supplement process itself is a "requirement." *See supra; see also Am. L. Prod. Liab.* 3d § 91:16.

The Court finds that, given the language of § 360k and the implementing regulations,[11] the Supreme Court's rationale in *Lohr,* and the Eighth Circuit's reasoning in *Brooks v. Howmedica,* PMA Supplement approval, without more, is not necessarily a "requirement" of federal law. The submission of a product to the FDA for pre-market supplement approval does not, in itself, amount to a specific federal requirement meriting preemptive effect. Instead, the Court will inquire whether the FDA, in this instance, has promulgated any ascertainable precondition to regulatory approval. The Court will carefully examine

[11] 21 C.F.R. § 808.1(d) "State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements."

the potential "federal requirements" and then compare those requirements to the relevant state laws.[12]

IV. Discerning the State Requirements and Comparing for Conflict

A. Strict liability and negligence claims

Plaintiffs allege that the Silzone valve was defective in design and/or formulation in that when the valves left defendant's hands the risks exceeded the benefits. Alternately, plaintiffs argue that the valves were defective in design or formulation in that they were more dangerous than an ordinary consumer would expect when used in their intended or reasonably foreseeable manner. Plaintiffs also allege the valves were defective due to inadequate warning, and that defendant failed to provide adequate post-marketing warnings. In addition, plaintiffs allege the valves failed to conform to the representation of defendant (in that they were not safe for use by consumers), and plaintiffs allege defendant failed to adequately test the valves.

Defendant argues that these claims are necessarily pre-empted because the FDA approved the device, and any inquiry into the approval process is forbidden "second-guessing" of the FDA. Plaintiffs argue that these claims are not pre-empted because the claims do not rely on any

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[12] The Court will address only the "main" claims common to the majority of plaintiffs. By not addressing a particular claim, the Court is not expressing an opinion on whether that ancillary claim would amount to a conflicting "requirement." However, defendant is not entitled to summary judgment on such claims, because defendant did not meet its burden of establishing that such claims conflict with a federal requirement.

state "requirement" different from any federal requirement. Plaintiffs suggest that because there was no "requirement" to continue selling Silzone after its safety was called into question, plaintiffs' strict liability (and negligence) claims cannot be preempted.

Device manufacturers are never "required" to sell devices, and therefore it seems that plaintiffs' first argument would totally eliminate preemption – a result that clearly is incorrect. Plaintiffs' next argument, however, is more persuasive. Plaintiffs note that the FDA encourages voluntary recalls and unilateral changes to warning labels. Although the *Brooks* Court rejected an argument premising liability on the failure to update a warning, plaintiffs' argument is distinguishable. In *Brooks,* the Eighth Circuit examined the plaintiff's evidence to discern (1) whether the FDA was aware of that particular risk when approval to the warning language was granted and (2) whether that risk was scientifically established either at the time of approval, or at the time the suit was brought. This inquiry implies that if the FDA had not been aware of the risk, plaintiff Brooks' failure to warn claim would not have been preempted. Applying that reasoning here, plaintiffs would have to establish that defendant knew of the particular risks during the PMA Supplement process, and that the risk is scientifically valid. Plaintiffs claim to have evidence of both, and point to specific facts in the record demonstrating a dispute of material fact.[13]

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[13] Plaintiffs claim both pre-approval and post-approval evidence. Plaintiffs point to evidence that defendant misrepresented the results of animal tests to the FDA because defendant failed to report the death of one of the subject animals. In addition, plaintiffs cite public reports from the medical community of high rates of stroke and other thromboembolic events, as well as allegedly high explant patterns. Plaintiffs

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Defendant has not, therefore, established that plaintiffs' strict liability failure to warn claims are pre-empted and summary judgment is inappropriate.[14]

Although the *Brooks* decision did not address a claim for design defect, the Court applies a similar rationale to deny defendant's motion for summary judgment as to those claims. As the Eighth Circuit explicitly stated in *Brooks,* a claim alleging failure to comply with FDA regulations is not preempted, because such a claim imposes no requirements different from or in addition to federal requirements. *Brooks,* 273 F.3d at 798-99. Preemption was nonetheless appropriate in the *Brooks* case, however, because the Eighth Circuit determined that plaintiff did not make such a claim. In contrast, plaintiffs here claim, and present evidence, that defendant "violated federal regulations . . . failed to meet regular reporting requirements, failed to report a known hazard to the FDA, [and] failed to comply with federal law in other respects." *Id.* at 799. Therefore, to the extent that plaintiffs' negligence and defective design claims hinge on violations of FDA requirements, the claims are not preempted, and summary judgment is not appropriate.

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claim these facts establish knowledge on defendant's part that the valve was problematic, yet defendant did not report the problems to the FDA.

[14] Defendant's argument would allow medical device manufacturers to wrongfully withhold data from the FDA, gain PMA or PMA supplement approval, and then be completely immune from liability based on that approval. This cannot be what Congress had in mind when it enacted the MDA because, in its judgment, medical device manufacturers needed to be more strictly regulated. *See Lohr,* 518 U.S. at 587 (noting that in the judgment of Congress the medical device industry needed more stringent regulation).

B. Implied and Express Warranty

Plaintiffs allege that defendant breached the implied warranty because the Silzone valve was not fit and safe for its intended use, the defects were present when the product left defendant's hands and the valves were defective, unmerchantable and not fit for their intended purpose. To support their argument that the implied warranty claim is not pre-empted, plaintiffs point to section 808 of chapter 21 of the C.F.R. which notes that "the following are examples of State or local requirements that are **not regarded as preempted** . . . requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as . . . the Uniform Commercial Code (**warranty of fitness**))." (Emphasis added.) Since many states, including Minnesota, have adopted the U.C.C. implied warranty provision, it appears that claims premised on the U.C.C. should survive preemption motions. *See Duvall v. Bristol-Myers-Squibb Co.,* 103 F.3d 324, 330, n.5 (4th Cir. 1996) ("Although the [Supreme] Court did not address a claim for breach of implied warranty in *Medtronic [v. Lohr],* we nevertheless determine that the reasoning of that decision requires a conclusion that state-law claims for breach of implied warranties are not preempted by § 360k(a)."). *But see Mitchell v. Collagen Corp.,* 126 F.3d 902, 915 (7th Cir. 1997) ("If the [plaintiffs] meant to allege an implied warranty, it is preempted.").

Similarly, plaintiffs cite several cases in which courts have explicitly held that express warranty claims are not preempted. Those cases seem correctly decided and the Court agrees that express warranty claims are not preempted, at least to the extent that the defendant makes express warranties in addition to the language (warranties

or warnings) required by the FDA. *See Mitchell,* 126 F.3d at 915 ("As we noted in our earlier opinion, [express] warranties arise from the representations of the parties and are made as the basis of the bargain between them. A state judgment based on the breach of an express representation by one of the parties does not necessarily interfere with the operation of the PMA, and therefore we cannot say that such a cause of action is preempted."). *See also Steele v. Depuy Orthopaedics, Inc.,* 295 F. Supp. 2d 439, 2003 U.S. Dist. LEXIS 21155, 2003 WL 22779079 at *14 (D.N.J. Nov. 20, 2003) (denying defendant's motion for summary judgment on preemption grounds as to plaintiff's breach of express warranty claims).

As evidence of particular express warranties that (allegedly) were breached, plaintiffs point to, among other things, an advertisement for Silzone which states, "With over 30,000 implants St. Jude Medical heart valves with Silzone coating continue our tradition of excellent clinical performance." Plaintiffs then note that in deposition, St. Jude employee Dr. Guzik admits that the "tradition of excellent clinical performance" was questionable. Plaintiffs argue this is a clear-cut example of a breach of express warranty. Plaintiffs also assert, and support with deposition testimony, that St. Jude sales representatives represented to heart surgeons that the Silzone valves were superior to the Masters Series because of the anti-microbrial properties of the silver in the Silzone.[15] Such a

[15] For example, a St. Louis thoracic surgeon averred that he implanted approximately fifty Silzone valves "because of its asserted anti-bacterial and anti-infection properties." This understanding, he continues, "came in significant part from statements made to me by a sales representative of St. Jude Medical . . . [who] informed me that the Silzone valve was an improvement over the existing St. Jude Master's

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representation was expressly forbidden by the FDA. St. Jude disputes that it made such representations, and points to statements by St. Jude managers to that effect. This disagreement highlights the disputed material facts. Plaintiffs have pointed to specific, admissible evidence raising disputed issues of material fact on these claims. Therefore summary judgment on pre-emption grounds must be denied as to the breach of warranty claims.

C. Inadequate warnings and labeling

Plaintiffs call this an "easy call" arguing that because Minnesota's duty to warn "requirements" mirror product manufacturers' duties under the FDCA and the FDA, there is no conflict. The trouble with plaintiffs' analysis is that the FDA, at least initially, determined that the labeling constituted an adequate warning. In fact, the FDA drafted some of the language, and approved all of the language.

Plaintiffs' argument continues – "despite knowledge [of risks] SJM never made or even proposed a single change to the Silzone labeling." At first blush, this argument is identical to that rejected by the Eighth Circuit in *Brooks*. However, the plaintiff in *Brooks* could not show (or simply failed to show) that the FDA was unaware of the risks when the labeling was approved. Here, plaintiffs argue that they can demonstrate that the FDA was unaware of certain risks as the label language was updated. Defendant argues that plaintiffs' claims are nonetheless

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Series valve because the Silzone coating on the valve sewing cuff would greatly reduce the incidence of post-surgery infection." (Plaintiffs' Appendix at Volume VI, Exhibit 21).

preempted, because to prove that the FDA was unaware of a given risk, plaintiffs will essentially have to prove fraud on the FDA – the inquiry rejected in *Buckman.* Defendant apparently would have the Court read *Buckman* so as to preempt any and all claims in which any inquiry into the FDA regulatory process is necessary.

It is difficult to accept such an expansive reading of *Buckman,* and such a reading would be difficult, if not impossible, to reconcile with the decision announced in *Lohr.* In addition, the *Brooks* Court had the benefit of the *Buckman* opinion, and nonetheless reasoned that the result might be different had plaintiff shown that the FDA was unaware of certain information. The Supreme Court in *Buckman* was addressing a cause of action emanating **exclusively** from federal regulations. This case does not present such a limitation. The critical distinction between *Lohr* and *Buckman* is not that a court or jury would have to examine what the FDA knew, and when it knew it. Instead the meaningful distinction is a fundamental difference in the very source of the cause of action. That is, in *Lohr,* the cause of action was based in traditional state tort law; in sharp contrast, the cause of action asserted in *Buckman* depended entirely on the regulatory relationship between the federal government and the FDA. In that dispositive way, the instant case is more similar to *Lohr,* and entirely unlike *Buckman.* In this case, the inadequate labeling and failure to warn claims are based on traditional tort causes of action – causes of action that have normally been the exclusive province of states. For that

reason, *Buckman* does not require preemption of these claims.[16]

Similarly, *Brooks* does not dictate a result in defendant's favor. Unlike the plaintiff in *Brooks,* the plaintiffs here have alleged, and have supported with specific evidence, that the FDA was not aware of the risk that the Silzone valve presented. In short, plaintiffs have raised disputed issues of material fact such that their inadequate warning and labeling claims survive summary judgment on the ground of preemption.

D. Consumer fraud & deceptive trade practices statutes

Like state law requirements under the U.C.C., the applicable regulation expressly states that claims under state unfair trade practices are not preempted. 21 C.F.R. § 808(d). Citing *Buckman,* defendant argues that plaintiffs' consumer fraud and deceptive trade practices claims are really "fraud on the FDA claims" in disguise, and are therefore preempted. Again, the Court does not find that *Buckman* extinguishes plaintiffs' claims at this stage of the litigation. Instead, the Court finds this case more

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[16] Legal commentators have made a similar distinction. *See, e.g.,* Thomas O. McGarity, *Beyond Buckman: Wrongful Manipulation of the Regulatory Process in the Law of Torts,* 41 Washburn L.J. 549, 572 (2002) ("Under *Medtronic [v. Lohr]* and its predecessors, plaintiffs should ordinarily be able to base actions against manufacturers of risky products on traditional common law negligence and strict liability theories without fear of preemption. As cases based upon negligence and strict liability go forward, evidence of attempts by the defendant to manipulate the regulatory process through fraudulent or misleading means should be admissible even if wrongful manipulation may not support an independent claim for relief.").

analogous to *Dawson ex rel. Thompson v. Ciba-Geigy Corp., USA,* 145 F. Supp. 2d 565 (D.N.J. 2001). In that case, the Court rejected defendant's preemption argument, noting:

> Plaintiffs' Complaint here does not allege a claim of "fraud on the FDA," but rather alleges that Defendants deceived the public, including Plaintiffs. The Supreme Court in *Buckman* expressly distinguished "fraud on the FDA" claims from other state tort claims for fraudulent labeling, such as those that the Court had previously addressed in *Medtronic v. Lohr,* 518 U.S. 470, 135 L. Ed. 2d 700, 116 S. Ct. 2240 (1996). *Buckman,* 121 S. Ct. at 1020. . . . *Buckman* thus clarified that traditional state tort law claims (even those which parallel FDCA requirements) are not necessarily preempted by the FDCA and are not necessarily the same as "fraud on the FDA" type claims. *Id.* Unlike the claims in *Buckman,* a finding of a violation of the FDCA is not a necessary element of Plaintiffs' claims, which rely on traditional state tort principles. Plaintiffs are not claiming a violation of the FDCA; their claims are confined to traditional state tort and fraud claims, similar to those in *Medtronic.*

Id. at 573. The Court finds that reasoning persuasive, and therefore denies defendant's pre-emption motion on the consumer fraud and deceptive trade practices claims.

E. Medical monitoring

In general, a medical monitoring plaintiff must establish exposure to a hazardous substance; that as a proximate result of exposure, plaintiff suffers a significantly increased risk of contracting a serious latent

disease; that increased risk makes periodic diagnostic medical examinations reasonably necessary, and that monitoring and testing procedures exist which make the early detection and treatment of the disease possible and beneficial. The parties' briefing did not address whether medical monitoring claims impose requirements different from or in addition to those imposed by federal requirements, and the Court determines that such claims do not. Therefore, defendant's motion for summary judgment is denied as to plaintiffs' medical monitoring claims.

V. Drug, Device, or Both

Plaintiffs also assert that they have raised a disputed issue of material fact as to whether the valve is a device, or is a combination drug and device. This distinction is important because the express preemption principles and case law discussed above do not apply to combination products or to drugs (§ 360k by its terms applies only to devices). Plaintiffs base this argument on their experts' opinions that the silver sewn into the valve interacts with the body more like a drug than a device. Plaintiffs assert that the FDA never determined that the valve is a device, rather than a drug, but that even if such a determination had been made, the Court is not bound by the FDA's determination. *See Tarallo v. Searle Pharmaceutical, Inc.*, 704 F. Supp. 653, 658 (D.S.C. 1988) (reasoning that because Congress defined the terms "drugs" and "device" the Court is not bound by an administrator's determination); *see also Callan v. G.D. Searle & Company*, 709 F. Supp. 662, 666 (D. Md. 1989) (finding that Copper 7 IUD was drug due to release of copper ions).

Defendant briefly addresses this argument, and states the FDA expressly considered the drug/device issue and classified the valve as a device. The Court reviewed the exhibits defendant identified, and from those exhibits, it appears that the FDA *considered* the drug or device issue. In particular, one exhibit defendant identifies is a portion of minutes from a June 1998 meeting, apparently of the Circulatory Systems Devices Panel of the FDA. Def. Appendix C, tab 32. That excerpt includes a discussion during which the drug/device distinction was addressed, but, at least in the portion submitted to the Court, there does not appear to be a conclusion or consensus reached. Defendant also suggests that all of Appendix C supports its argument that the FDA expressly determined that the valve is a device. The Court carefully reviewed the documents submitted in Appendix C, and did not uncover any indication that the FDA explicitly determined that the valve is a device, rather than a drug. The Court notes, however, that Appendix C does contain many instances of defendant making that assertion to the FDA, and the FDA continually referred to the valve as a device.

The Court owes no deference to an FDA "classification" where it is made simply for "administrative convenience" and does not reflect the considered view of the agency. *See Tarallo,* 704 F. Supp. at 658. The Court finds plaintiffs' argument that the valve more closely resemble a drug/device combination to be intuitively persuasive. However, because the Court finds that plaintiffs' claims are not pre-empted and this drug/device issue requires more extensive analysis, the Court will not decide at this time whether the heart valve with Silzone coating is a drug, a device or a combination.

VI. What approval? 510k or PMA Supplement

Plaintiffs finally argue that because the approval process here was more like the abbreviated 510k-equivalence process than the PMA Supplement-safety process, preemption should not apply. *See Brooks,* 273 F.3d at 794 ("Section 510(k) approval is a mere grant to market; it imposes no "requirements" of its own.") (Citing *Lohr,* 518 U.S. at 493). Plaintiffs suggest that the Court simply needs to determine that the FDA never made a determination of the efficacy of the Silzone coating.

The FDA, at least ostensibly, approved the valve via the PMA Supplement. (March 24, 1998 Letter from Susan Alpert, Director, Office of Device Evaluation stating "The Center for Devices and Radiological Health (CDRH) of the [] FDA has completed its evaluation of your premarket approval application (PMA) supplement."). On the other hand, it is clear that the FDA never determined that the Silzone coating was "effective." In fact, the FDA explicitly precluded defendant from making claims regarding the efficacy of the Silzone coating. *Id.* ("The labeling of the device must not contain or imply any claims that the Silzone Coating is effective in reducing the incidence of endocarditis."). Equally clear, nonetheless, is that the valve itself continued to be considered effective as a heart valve. The parties ask the Court to determine if issuing a PMA Supplement approval without making a finding of efficacy, invalidates the approval, transforms the approval into 510(k) approval, or is an abuse of agency discretion.

A separate, but related argument is that the approval, whichever approval it was, was lost when defendant failed to comply with FDA guidelines, or if not at that point, at least once the product was voluntarily recalled. "Please

comply with the above guidelines. We do not want to do anything that will jeopardize our own FDA approval." (Memorandum from Hosek to U.S. Sales Force at Plaintiffs' Appendix Vol. VI, Ex. 79.)

The FDA classified St. Jude's actions as "a recall." The Administration noted, "We are assigning recall numbers to [Silzone valves] . . . We are classifying the firm's actions as a voluntary recall. We consider the devices to be adulterated and misbranded." (March 20, 2000, Memorandum from Cardiovascular and Neurological Devices Branch at Plaintiffs' Appendix Vol. VI, Ex. 100.) Similarly, a March 22, 2000 letter from Edwin Dee to St. Jude noted, "We agree with your firm's decision to recall [listing of specific device identifying numbers] . . . We have reviewed your action and conclude that it meets the formal definition of a 'Recall'. This is significant, as your action is an alternative to a Food and Drug Administration legal action to remove the defective products from the market." (Plaintiffs' Appendix Vol. V, Ex. 24.)

Defendant suggests that this letter is "out of context" and that the Silzone valve in fact has never been recalled (specifically, counsel for St. Jude stated at oral argument that "The adulterated and defective language that the plaintiffs pick on from the correspondence is drawn out of context. It doesn't represent any regulatory finding or conclusion."). The Court hesitates to characterize defendant's argument too harshly, however, it is difficult to read the FDA's March 20, 2000 and/or March 22, 2000 correspondence and find any ambiguity, regardless of context. The FDA clearly indicates that the device is "adulterated and misbranded." The recall is significant because it is "an alternative to [FDA] legal action to remove the product from the market." Despite defense counsel's arguments,

St. Jude appears to recognize that the Silzone valve is not marketable absent additional approval from the FDA. *See Affidavit of Alan Flory* at Plaintiffs' Appendix, Vol. II, Tab. 2(A) page 258. (Q: "The fact that the PMA Supplement has not been withdrawn doesn't mean that you're perfectly free to go out and market this product again, unless FDA says you can do it. Isn't that fair?" A: "That's true. . . . Unless we put in a PMA supplement and notify [the FDA] that we have the clinical data that we said we would gather before we put it back on the market.")

The Court finds persuasive plaintiffs' argument that the Silzone valve no longer has FDA approval. At this time, however, the Court need not determine how the withdrawal of approval impacts plaintiffs' claims. Similarly, the Court will not resolve whether the Silzone valve's approval was via the PMA supplement or was 510k approval, because the Court has found that plaintiffs' claims are not pre-empted. The Court will not scrutinize such an involved issue without the benefit of thorough briefing on this specific question. The Court's research has revealed that plaintiffs' argument regarding types of approval (PMA versus 510k) is not novel, but the Court has been unable to find a reported decision in which a court **analyzes** the method of approval to determine independently whether the approval was PMA or 510k. *See, e.g., Steele v. Depuy Orthopaedics, Inc.*, 2003 U.S. Dist. LEXIS 21155, 2003 WL 22779079 at *5 (D.N.J. Nov. 20, 2003) (acknowledging plaintiffs' argument that the approval at issue was more akin to the abbreviated 510k, and apparently rejecting the argument, but not discussing the issue).

MOTIONS TO STRIKE

I. Defendant's motion to strike affidavits of plaintiffs' three experts

Defendant moves to strike the affidavits of Gregory Wilson, Devin Healy, and Suzanne Parisian, arguing that the expert reports violate "fundamental rules of evidentiary admissibility." Defendant asserts four "compelling reasons" to strike the affidavits, including (1) the opinions are irrelevant, (2) the expert's testimony is not the proper subject of expert opinion under controlling law, (3) the opinions are simply legal conclusions "recast as expert opinion," and (4) the experts are not qualified.

For the purposes of this motion, the Court denies the motion to strike. The material is relevant, and the Court assures defendant that the Court will reach its own conclusions regarding the law and will not be misled by plaintiffs' experts. The Court might well be more cautious in allowing a jury to consider such opinions. Finally, the Court finds that the experts are adequately qualified given each expert's education, training and experience.

II. Plaintiffs' Motion to Strike the Affidavits of Alan Flory and Diane Johnson.

Flory is an employee of St. Jude Medical. Johnson is a former FDA employee who is presented as having expertise in the field of heart valve regulation and the PMA process. Plaintiffs object on the grounds of hearsay and lack of personal knowledge. Plaintiffs note that in deciding a motion for summary judgment, the Court may not consider affidavits that do not satisfy the requirements of Fed. R. Civ. P. 56(e).

Plaintiffs argue that the information in Flory's affidavit is based on hearsay. In addition, plaintiffs suggest that Flory admitted during deposition that he has no personal knowledge that St. Jude complied with every applicable FDA regulatory requirement as he averred. The basis for the objection to the Johnson affidavit appears to be lack of personal knowledge.

The Court denies the motion to strike for purposes of this summary judgment motion. Although the Court must not rely on evidence which would be inadmissible, it is not necessary to strike either affidavit. Plaintiffs have preserved their objections, and the Court can sift through the affidavits to determine what portions, if any, would be inadmissible and therefore will not be considered for the purposes of summary judgment. It appears to the Court that Johnson is offered as an expert, and therefore the personal knowledge objection is inapplicable.

III. Plaintiffs' motion to strike the attachments to defendant's reply brief

The Court granted defendant a significant page and time extension for its reply brief. Defendant used its full page allotment, and also attached additional argument, in the form of "charts" as exhibits. These exhibits are improper, and given the Court's reasonableness in granting the page and time extension, the Court finds defendant's additional argument in the guise of "exhibits" unfortunate. The Court therefore strikes the argumentative portions of the "charts" (specifically, the portions preceding the numbered tabs). However, the charts also serve as a table of contents, and the Court will continue to use the table of contents portion.

ORDER

Based upon the foregoing, the submissions of the parties, the arguments of counsel and the entire file and proceedings herein, **IT IS HEREBY ORDERED:**

1. Defendant's motion for summary judgment [Docket No. 67] is **DENIED;**

2. Defendant's motion to strike the affidavits of Gregory John Wilson, Kevin E. Healy, and Suzanne Parisian [Docket No. 219] is **DENIED.**

3. Plaintiffs' motion to strike the affidavits of Alan R. Flory and Diane Johnson [Docket No. 208] is **DENIED.**

4. Plaintiffs' motion to strike appendices to St. Jude's reply in support of motion for summary judgment [Docket No. 223] is **GRANTED in part and DENIED in part as described above.**

DATED: January 5, 2004
at Minneapolis, Minnesota.

JOHN R. TUNHEIM

United States District Judge

CAUSE NO. 312543-~~401~~[402]
(Consolidated)

ESTATE OF	§	**IN THE PROBATE COURT**
JEAN BAKER	§	**NUMBER ONE (1) OF**
	§	
DECEASED	§	**HARRIS COUNTY, TEXAS**

ST. JUDE MEDICAL'S MOTION FOR AND BRIEF IN SUPPORT OF SUMMARY JUDGMENT

(Filed Jan. 7, 2002)

I

INTRODUCTION

St. Jude Medical, Inc. moves for summary judgment because plaintiffs' tort claims are preempted by federal law.

In support of its motion, St. Jude Medical provides this Court with incontrovertible evidence demonstrating that the heart valve at issue in this case underwent the federal Food and Drug Administration's rigorous Premarket Approval (PMA) and PMA Supplement process before it was put on the market. The FDA concluded the heart valve was sufficiently safe and effective for its intended use to permit marketing and sale, and was involved in everything from testing the valve to revising its package label. Even then, after the FDA approved the device for marketing, it continued to be subject to FDA regulation and control, and at all times St. Jude Medical fully complied with all FDA requirements for the heart valve.

As the Texas Supreme Court acknowledged in *Worthy v. Collagen Corp.*, 967 S.W.2d 360 (1998), when this type of

medical device is subject to this exact type of FDA regulation, any state tort claim that contends the device nevertheless is defective contradicts federal law, and therefore is preempted by it. Application of the controlling law to these incontrovertible facts compels the conclusion that plaintiffs' tort claims are preempted by federal law in this case. The

* * *

III

LEGAL ARGUMENT

A. When Undisputed Facts Demonstrate A Complete Defense As A Matter Of Law, Summary Judgment Must Be Granted

Summary judgment motions provide courts with a mechanism to cut through the parties' pleadings and dispose of "patently unmeritorious claims" when there is no genuine dispute of material fact and the defendant is entitled to judgment as a matter of law. Tex. R. Civ. Proc. R. 166a; *Worthy,* 967 S.W.2d at 365, 377 *Burns v. Thomas,* 786 S.W.2d 266 (Tex. 1990); *Houston v. Clear Creek Basin Authority,* 589 S.W.2d 671 (Tex. 1979). A defendant can meet its summary judgment burden of showing an action has no merit by establishing that there is a complete defense to it. *See Worthy,* 967 S.W.2d at 365, 377 (summary judgment was proper due to affirmative defense of preemption where defendant established its device went through the PMA and PMA Supplement process). Once that showing is made, the plaintiff cannot avoid summary judgment unless he or she demonstrates a triable issue of fact exists as to that defense; in doing so, the plaintiff cannot rely on the mere allegations or denials in the

complaint. *Hidalgo v. Surety Sav. & Loan Ass'n,* 462 S.W.2d 540, 543 (Tex. 1971).

In accord with Rule 166a, St. Jude Medical is entitled to summary judgment because application of controlling law to its incontrovertible evidence regarding FDA regulation of the Silzone® heart valve – including through the PMA and PMA Supplement process – demonstrates the complete affirmative defense of preemption. While St. Jude Medical's supporting evidence is voluminous, that is so merely because of the comprehensive nature of the FDA's regulation of its device – it is ***not*** the result of any complexity of the preemption issue or potential conflict in the evidence. Simply put, the FDA's regulation of the medical device in question compels the conclusion that plaintiffs' action is preempted by federal law and must be dismissed.

B. The Supremacy Clause Requires The Preemption Of State Law By Federal Law When – As With The MDA – That Was Congress' Intent

The affirmative defense of preemption is a product of our nation's dual federal-state system. Under the Supremacy Clause of the Constitution, state law must give way to federal law when Congress intends that preemptive result. *Brooks,* 2001 WL 1568430, at *6 (citing U.S. Const., Art. VI, cl. 2); *see also Crosby v. National Foreign Trade Council,* 530 U.S. 363, 372 (2000) ("A fundamental principle of the Constitution is that Congress has the power to preempt state law"). Congress evidences an intent to preempt state law either through ***express*** statutory language, or by creating a federal statutory scheme or purpose that ***implies*** a preemptive intent. *Brooks,* 2001 WL 1568430, at *6 (citing *Cipollone v. Liggett Group, Inc.,* 505 U.S. 504,

516 (1992)). Under both express and implied preemption principles, plaintiffs' claims here cannot stand.

C. Plaintiffs' Tort Claims Are Expressly Preempted By The MDA

When Congress enacted the MDA and endowed the FDA with the authority it uses to regulate medical devices, it sought to protect innovations in device technology from being "stifled by unnecessary restrictions." H.R. Rep. No. 94-856, at 12 (1976). To accomplish that goal, Congress included an express preemption clause, a "general prohibition on non-Federal regulation," in the MDA. *Id.* at 45. That express preemption clause, which also serves to safeguard the uniformity of the federal regulatory regime for ensuring the availability of safe and effective medical devices, broadly provides that no State may impose "any requirement" relating to the safety or effectiveness of a medical device that "is different from, or in addition to, any requirement applicable ... to the device" under federal law. 21 U.S.C. § 360k(a).

The Texas Supreme Court, the Fifth, Sixth, Seventh and Eighth Circuit Courts of Appeal – plus numerous district courts and state courts – all have held that the MDA's express preemption clause bars state tort claims involving any device that has been through the PMA or PMA Supplement process. *Worthy,* 967 S.W.2d at 376; *see also Brooks,* 2001 WL 1568430, at *8-*11 (8th Cir.); *Martin,* 254 F.3d 584-85 (5th Cir.); *Kemp,* 231 F.3d at 226-2 (6th Cir.); *Mitchell,* 126 F.3d at 911 (7th Cir.); *Fry v. Allergan Med. Optics,* 695 A.2d 511, 516 (R.I. 1997); *Green v. Dolsky,* 685 A.2d 110, 117 (Pa. 1996). ***In fact, one federal court has found that the very PMA Supplement***

process that the St. Jude Medical Masters Series valve went through in 1995 has an express preemptive effect on state tort claims. *See Enlow v. St. Jude Medical, Inc.*, ___ F. Supp. 2d ___, 2001 WL 1360204 (W.D. Ky. Oct. 18, 2001).

Each of these cases, including *Worthy,* involved the direct application of the leading U.S. Supreme Court case on the express preemption issue – *Medtronic, Inc. v. Lohr,* 518 U.S. 470 (1996) ("*Lohr*"). Accordingly, the result here should be the same: because the heart valve at issue is the product of the PMA and PMA Supplement process, plaintiffs' state tort claims are preempted.

As Texas recognizes, the *Lohr* preemption analysis has two key components:

- ***First,*** "specific" federal requirements can be preemptive of "specific" state requirements. *See Worthy,* 967 S.W.2d at 369-70; *see also Lohr,* 518 U.S. at 500; *id.* at 506-07 (Breyer, J., concurring); and

- ***Second,*** state tort claims ***can*** be a specific state "requirement" and thus can be preempted. Even though tort law is general and does not specifically target medical devices, when a jury holds a defendant liable for employing or not employing a certain warning or design, for example, it is imposing a specific requirement on the medical device using the threat of civil liability. *See Worthy,* 967 S.W.2d at 71; *see also Lohr,* 518 U.S. at 504-05 (Breyer, J., concurring); *id.* at 509 (O'Connor, J., concurring in part and dissenting in part); *Martin,* 254 F.3d at 579-83.

Using this framework, *Lohr* considered the preemptive effect of the MDA's express preemption clause on state tort claims where the medical device at issue had been approved for sale only through the less-rigorous "510(k)" or "pre-market notification" process, not the intensive PMA or PMA Supplement process. In a fractured opinion, the *Lohr* Court held that the less-rigorous 510(k) process focused on "entirely generic concerns about device regulations generally," such as preventing the development of monopolies by allowing new competitors to market devices that are substantially equivalent to devices available before the MDA. Accordingly, the 510(k) process did not give rise to any "specific" federal requirement, and thus did not preempt state tort claims. *See Lohr,* 518 U.S. at 492-93, 501.

The more-restrictive PMA and PMA Supplement process does satisfy the *Lohr* preemption framework, however. Unlike the 510(k) process, the PMA and PMA Supplement, process ***does*** result in FDA-imposed "specific federal requirements" applicable to a medical device.[4] The Texas Supreme Court, the Fifth, Sixth, Seventh and Eighth Circuits, plus numerous district courts and other state courts, all have so held. *See Worthy,* 967 S.W.2d at 369-70; *see also Brooks,* 2001 WL 1568430, at *8; *Martin,*

[4] In a case with "facts and circumstances" closer to the 510(k) process in *Lohr* than the PMA and PMA Supplement process in *Worthy,* the intermediate appellate court in *Herring v. Telectronics Pacing Systems, Inc.*, 964 S.W.2d 753, 755 n.2 (Tex. App. 1998), declined to uphold the express preemption defense. In this case, however, it cannot be disputed that St. Jude Medical's device went through the more rigorous PMA and PMA Supplement process, placing it squarely within *Worthy's* holding.

254 F.3d at 584-85; *Kemp,* 231 F.3d at 226; *Mitchell,* 126 F.3d at 911; *Fry,* 695 A.2d at 516; *Green,* 685 A.2d at 117.[5]

Moreover, the vast majority of lower courts also hold – as did *Lohr* – that state tort claims can impose requirements on the warnings, design, or manufacturing of medical devices, and can therefore amount to a "specific" state requirement triggering preemption. *See Worthy,* 967 S.W.2d at 376-77; *see also Martin,* 254 F.3d at 579-83;

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[5] In contrast, only one other federal circuit court and one state supreme court did not find PMA approval to be preemptive – *Goodlin v. Medtronic, Inc.,* 167 F.3d 1367 (11th Cir. 1999), and *Weiland v. Telectronics Pacing Systems, Inc.,* 721 N.E.2d 1149 (Ill. 1999). The decisions in these two cases are flawed, internally inconsistent, and unlikely to survive.

For example, the *Goodlin* court found certain requirements imposed through the PMA process not to be "specific" while acknowledging that other aspects were. 167 F.3d at 1376. The court then concluded that the FDA's conditions of approval – which bar modification of a device without FDA consent – were specific requirements, but somehow were not requirements "applicable to the device" exclusively. *Id.* These holdings are internally inconsistent and – more importantly – contrary to *Lohr,* which focused on whether federal requirements were specific or general, not whether they were applicable exclusively to one device. *See* 518 U.S. at 500 ("federal requirements must be 'applicable to the device' in question" under FDA regulations to give rise to preemption).

Weiland, in contrast, found that all aspects of the PMA process were not specific. *See* 721 N.E.2d at 1152. It is not clear what factual showing was before that court, but the decision is based on the patently erroneous conclusion that the PMA process "imposes no ascertainable requirement on the manufacture or design of the device" [id.] – a conclusion that is not supported in this case. The decision also is erroneous because it is based on the assumption that the PMA process only allows the FDA to assure "the minimal safety of medical devices". *Id.* at 1153. This premise is inconsistent with both *Lohr* which recognized the PMA's "reasonable assurance" of safety and efficacy to be a substantial requirement, and *Buckman,* which reasserted the rigor of the PMA process and noted the delicate balancing act the experts at the FDA employ in weighing countervailing considerations.

Kemp, 213 F.3d at 224; *Mitchell,* 126 F.3d at 913-14; *Papike v. Tambrands, Inc.,* 107 F.3d 737, 741 (9th Cir. 1997); *Fry,* 695 A.2d at 517; *Green,* 685 A.2d at 117-18.[6]

Because the medical device at issue in this lawsuit has been through the PMA and PMA Supplement process – just like the devices in *Worthy, Brooks, Martin, Kemp,* and *Mitchell* – this Court must likewise conclude that plaintiffs' claims against St. Jude Medical are preempted by the MDA.

First, it cannot be disputed that St. Jude Medical marketed its Masters Series valve with Silzone®-coated sewing cuff only after successfully navigating the rigorous PMA Supplement process, or that its precursor heart valve went through the rigorous PMA process. As described above, the FDA thoroughly reviewed the PMA Supplement for the Silzone® valve, routinely demanded additional data, and – significantly – approved the type of testing and testing specifications for the valve. (*See* Flory Aff. ¶¶ 46-59)

Moreover, the FDA specifically approved the language on the valve's warning labels and promotional materials, specifically approved its design composition (including the use of Silzone® to coat the sewing cuff), and specifically

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[6] Only one federal circuit court or state supreme court defied *Lohr* and concluded otherwise. That case, *Oja v. Howmedica, Inc.,* 111 F.3d 782, 789 (10th Cir. 1997), was one of the first to attempt to decipher *Lohr* and plainly misinterpreted it in many ways – for example, the court never considered whether a state law tort claim could impose a requirement, even as it acknowledged that such a determination was necessary. *Id.* at 788. It also did *not* involve a device approved through the PMA process, and thus does not inform the issues before this court, let alone control them.

imposed certain manufacturing procedures. (*See* Flory Aff. ¶ 59) As *Kemp* explains, "'PMA approval by the FDA constitutes approval of the product's design, testing, intended use, manufacturing methods, performance standards and labeling' and is 'specific to the product.'" *Kemp,* 231 F.3d at 226-27 (quoting *Mitchell,* 126 F.3d at 913).

And the FDA's close involvement with each of these aspects of the Silzone® valve did not end with the PMA Supplement approval. As St. Jude Medical's evidence amply relates, the FDA did carry out its duty to conduct rigorous post-marketing regulation as well. (*See* Flory Aff. ¶¶ 59-65) The net result is that the FDA did impose "specific" warning label, design, and manufacturing requirements on the Silzone® valve.

Second, the product liability cause of action that plaintiffs allege clearly seeks to impose state law requirements that are different from or in addition to those imposed by the FDA.

* * *

complies with FDA regulations but remains at risk of civil litigation nevertheless, those prospective and realized liabilities cause a substantial financial drain that inhibits medical research and innovation and, ultimately, hurts patients by limiting treatment options. Any failure to afford the MDA its full preemptive effect thus frustrates the very policy of promoting patient safety instead of protecting it. Because allowing plaintiffs' claims to proceed would disrupt the FDA's regulatory regime and frustrate its purpose, those claims are impliedly preempted.

IV

CONCLUSION

Because the FDA has reviewed and actively regulated every aspect of St. Jude Medical's Masters Series mechanical heart valve with Silzone®-coated sewing cuff that plaintiffs now challenge with their state-law tort claims, the defense of preemption requires that judgment be entered for the defendant. The valve at issue went through the PMA and PMA Supplement process, and the *Worthy, Mitchell, Kemp, Martin,* and *Brooks* cases compel the conclusion that plaintiffs' tort claims are expressly preempted by section 360(k) of the Medical Device Amendments.

In addition, the FDA's determination that the PMA supplement demonstrated the Silzone® valve to be sufficiently safe and efficacious, and its direct regulation of the valve's labeling, design propriety, and appropriate manufacturing standards, all would be directly contradicted by plaintiffs' tort claims if they were to prevail at trial. Accordingly, plaintiffs' tort claims also are impliedly preempted under the analysis set forth by the Supreme Court in *Buckman.*

* * *

No. 312543 ~~401~~ [402]

ESTATE OF	§	**IN THE PROBATE COURT**
JEAN BAKER	§	**NUMBER ONE (1) OF**
	§	
DECEASED	§	**HARRIS COUNTY, TEXAS**

PLAINTIFFS' RESPONSE TO MOTION FOR SUMMARY JUDGMENT

(Filed Apr. 18, 2002)

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reasonable inference must be resolved in the nonmovant's favor. *See Science Spectrum, Inc. v. Martinez,* 941 S.W.2d 910, 911 (Tex. 1997) (citing *Nixon v. Mr. Property Management Co.*, 690 S.W.2d 546, 548-49 (Tex. 1985)).

Controverting Evidence

In this response, plaintiffs rely on the following summary judgment controverting evidence:

1. Affidavit of Neil vanHooydonk (including documents referenced therein and/or attached thereto);
2. FDA PMA Supplement approval letter and other referenced documents produced by St. Jude in discovery;
3. Referenced portions of the deposition of defendant Dr. Jim S. Garza,
4. Referenced portions of the deposition of defendants' designated FDA expert, Diane Johnson;
5. Referenced portions of the deposition of defendants' designated representative Laxmi Peri;
6. Referenced portions of the deposition of defendants' designated representative, Alan Flory;
7. The post-mortem report on the body of Jean Baker; and
8. Public records from the United States Department of Health and Human Services, Food and Drug Administration.

Argument

I. No Preemption Because the Product is Not Deemed "Safe" by the FDA

A. The Nature of Federal Preemption Claims

The doctrine of preemption arises from the Supremacy Clause of the United States Constitution, which commands that the laws of the United States: "shall be the supreme law of the Land; . . . any Thing in the Constitution or laws of any State to the contrary notwithstanding."

Art. VI, cl. 2, UNITED STATES CONST.; *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 540 (2001). In determining whether any particular state law is preempted under the Supremacy Clause, the court must determine whether Congress, in enacting the statute, intended that it would be preemptive of state law claims. *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 484 (1996).

Remedies for products liability, negligence, and breach of warranty have traditionally been developed by the states under their historic police powers. *Id.* In considering preemption of such remedies, the courts must: "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Id.* at 485. Stated differently, the courts must engage in a presumption *against* preemption, unless it manifestly appears that Congress intended to preempt a state law remedy. *Cipillone v. Liggett Group, Inc.*, 505 U.S. 504, 518, 523 (1992).

In 1976, in response to concerns about the Dalkon Shield, the United States Congress passed the Medical Device Amendments of 1976 (MDA). *Medtronic,* 518 U.S. at 476. The MDA classified medical devices into three categories, and set up three procedures for persons seeking approval to manufacture and market such devices. These procedures range from the relative ease of demonstrating that the product is substantially equivalent to a product on the market before 1976 (a 510(k) submission), to the extremely rigorous full Premarket Approval (PMA) application. The PMA Supplement falls somewhere between the two, depending on the particular product

involved.[26] For each of the approval processes, there are varying requirements imposed by the FDA.[27]

The MDA provides, in section 360k, that no state can establish a requirement that is different from, or in addition to, any requirement placed on the device by the FDA. *Id.* at 481-82. The preemption argument is that a state court judgment, based on a finding that the product is unsafe, defectively designed or marketed, *etc.*, can constitute a state regulation that is different from or in addition to the requirements imposed by the FDA. *Worthy v. Collagen Corp.,* 967 S.W.2d 360, 368 (Tex. 1998). The argument has been rejected entirely with respect to 510(k) approvals, but accepted in some specific and limited contexts with regard to some full PMA applications. *See Medtronic,* 518 U.S. at 503, *and Worthy,* 967 S.W.2d at 377.

In this case, the abbreviated PMA Supplement process and approval for the product clearly could never overcome the presumption against preemption, as explained more fully below. However, the point is moot because the product in issue before the court does not have any FDA approval as to its safety or efficacy with which any state court judgment could possibly conflict.

State remedies can *only* be preempted if they conflict with or add to an existing and inconsistent counterpart federal regulation. *Medtronic,* 518 U.S. at 500. According to seven members of the United States Supreme Court:

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[26] vanHooydonk Aff.

[27] *Id.*

> [t]he statute and regulations, therefore, require a careful comparison between the allegedly pre-empting federal requirement and the allegedly preempted state requirement to determine whether they fall within the intended preemptive scope of the statute and regulations.

Id. The upshot of that clear statement of law is that if there is no existing federal regulation with which the state court judgment might conflict, preemption cannot possibly apply. *Id.*

B. FDA Determines the Product to be "Adulterated," "Misbranded," and "Defective"

The terms "PMA" and "PMA Supplement" necessarily infer that the product has the "approval" of the FDA to be "safe" enough to be marketed in the United States. *Medtronic,* 518 U.S. at 475, 477. As explained above, it is this approval of the sale of the product that gives rise to the preemption argument. Critically in this case, though, St. Jude does *not* have the approval of the FDA to market these devices in this country. *Indeed, unless St. Jude were to obtain a new Premarket Approval for the Silzone-coated valves, it would be a criminal act to sell the product.*[28]

It is true that the Silzone-coated valves initially received PMA Supplement approval, subject to certain continuing conditions, in March 1998. However, on January 21, 2000, St. Jude "voluntarily" recalled the product,

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[28] 21 U.S.C. § 331(a).

due to an alarming level of reports of the very type of paravalvular leaks which caused Jean Baker's death.[29]

On March 20, 2000, the FDA made an express determination that the Silzone valves were "adulterated and misbranded because there is a statistically significant higher rate of paravalvular leaks with the silver ion 'Silzone' coated sewing cuffs leading to valve explants."[30] Two days later, on March 22, 2000, the FDA advised St. Jude that it agreed with the "voluntary" recall of the product as: "an alternative to a Food and Drug Administration legal action to remove the defective products from the market."[31]

Under federal law, a medical device is "adulterated" only if it is, or purports to be, a device which is subject to performance standards under federal law, unless the device is in all respects in conformity with such standards. 21 U.S.C. §§ 360(d); 351(e). A medical device is "misbranded" only if it is: "health-endangering when used as prescribed." *See* 21 U.S.C. § 352(j). The distribution of a medical device which has been determined by the FDA to be adulterated *or* misbranded is a violation of federal law. 21 USC § 331(a). Thus, there is no existing finding by the FDA that this product is safe, effective, or approved for sale. To the contrary, the FDA unquestionably is in full agreement with the plaintiffs that the product is defective, adulterated, and misbranded.

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[29] vanHooydonk Aff.

[30] FDA documents, p. 300220.

[31] FDA documents, p. 001367.

Indeed, since there is no FDA determination with which the jury finding in this case could possibly conflict, it is disingenuous to suggest that federal law preempts the plaintiffs' causes of action. There is no possibility that a finding that the product is unsafe by a Texas jury could interfere with any existing FDA determination. Accordingly, the preemption doctrine cannot be applied. *Medtronic,* 518 U.S. at 500.

C. FDA Conditional Supplement Approval Automatically Invalidated by St. Jude Failure to Report

When the FDA approved the PMA Supplement, authorizing the use of the Silzone coatings in March 1998, it only did so subject to specific and ongoing conditions. Under the express terms of the approval, any failure to comply with these conditions invalidated the approval. These conditions required that St. Jude:

a. Not market the product with any claim or implication that the Silzone coating was effective in the prevention of endocarditis;

b. Submit post-approval reports to the FDA at intervals of one year;

c. Carefully track, to the final user or patient, each device so that they could be located quickly if serious problems were determined to be occurring with the product;

d. Submit a new PMA Supplement when any unanticipated adverse effect, increase in the incidence of adverse effect, or device failure, was encountered;

e. Submit, within 10 days of having knowledge, any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that was attributable to the device; and

f. Report any time St. Jude received or otherwise became aware of any information, from any source, that suggested that the device may have caused or contributed to a serious death or injury, or had malfunctioned such that it would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, *within 30 days of becoming aware of a reportable death, injury, or malfunction, or within 5 days of becoming aware that a reportable event required remedial action to prevent an unreasonable risk of substantial harm to the public health.* (emphasis added).[32]

The PMA Supplement approval expressly provided that a failure to comply with *any* of these continuing conditions of approval as set out above would: "invalidate this approval order."[33] The reports required under (d), (e), and (f) above must be submitted because such reporting would prevent an unreasonable risk of substantial harm to the public health. 21 C.F.R § 803.3(y). Accordingly, the adverse event reporting conditions are clearly material to the approval.

Attached hereto as Appendix A is a table of the information known to St. Jude at various points in time. By July 31, 1999, almost four months before Jean Baker's implant, St. Jude was aware that certain adverse events related to the Silzone-coated valve had occurred in the

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[32] FDA documents, p. 100861-100867.

[33] *Id.*

United Kingdom.[34] However, St. Jude did not timely submit any of the required reports to the FDA regarding these known complications. As a result, the conditional FDA approval was invalidated and became of no effect at that time by its express terms.

By November 6, 1999, when 97% of St. Jude's AVERT study was completed, St. Jude also knew that these life-threatening paravalvular leaks were occurring with alarming frequency in the United States.[35] Yet, St. Jude still did not submit the required reports to the FDA until January 21, 2000. This was an additional invalidating event.

These were not insignificant incidents. To the contrary, the early reactions were so significant that on November 22, 1999, the Silizone-coated valves were recalled in the United Kingdom.[36] Clearly, the reactions and recall in the United Kingdom, particularly combined with the AVERT complications, were sufficient to mandate immediate reporting to the FDA under conditions (d), (e), and (f), as quoted above. However, St. Jude wholly failed to do so for months, thus clearly invalidating the approval in accordance with its express terms.

As a result of St. Jude's uncontested failure to comply with the continuing conditions of approval, when Ms. Baker underwent mitral valve replacement surgery no valid FDA approval existed for the prosthetic valve she received. Of course, Ms. Baker and her physicians were

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[34] Refer to attached Appendix A, a table of the adverse events known by St. Jude long prior to the January 21, 2000, recall.

[35] Refer to Appendix A.

[36] Refer to Appendix A.

ignorant of that fact, again due to St. Jude's failure to comply with the express conditions of approval before and after the implant, as well as St. Jude's negligent failure to carry out its duty to notify Dr. Garza after January 21, 2000.[37]

D. No Preemption Because State Law Claims are Consistent with the Requirements of the Medical Device Amendments

As explained by the Texas Supreme Court in *Worthy,* "[t]he more specific a federal requirement under the MDA is, the more likely that that requirement will be preemptive." *Worthy*, 967 S.W.2d at 369. Conversely, the more general a requirement, the less likely it is to be preemptive. The overarching concern of the MDA is: ". . . that preemption occur only where a particular state requirement threatens to interfere with a specific federal interest." *Id.* quoting *Medtronic,* 518 U.S. at 500.

The term "requirement" for purposes of preemption, applies only to specific requirements applicable to a specific device. *Medtronic,* 518 U.S. at 498 (citing 21 C.F.R. 808.1(d)). For purposes of preemption, MDA labeling regulations, requiring the inclusion of information regarding, *inter alia*, relevant hazards, contradictions, side effects, and precautions, are too general to trigger preemption. *Id.* at 501. The MDA's "Good Manufacturing Practices" and labeling requirements are also not specific enough to have preemptive effect. *Id.*

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[37] Garza Depo., p. 141, l. 21.

Additionally, state common law claims are not specific to a particular medical device and as such are general obligations that are no threat to federal MDA requirements. *Id* at 501-02. By way of example, the legal duty that is the predicate for a negligence claim is the general duty of every manufacturer to use due care to avoid foreseeable dangers in its products. Similarly, the predicate for the failure to warn claim is the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use. *Id.* These general obligations are no threat to federal requirements, but in fact are entirely consistent:

> These state requirements therefore escape preemption, not because the source of the duty is a judge-made common law rule, but rather because their generality leaves them outside the category of requirements that 360k envisioned to be with respect to specific devices. . . .

Medtronic, 518 U.S. at 502.

Moreover, a state *remedy* does not create a federal conflict. Federal preemption applies not to state *remedies,* but to state *requirements. Id.* at 496-97. Even then, the United States Supreme Court is quite clear a federal statute preempts a state requirement only if:

> the state requirement actually conflicts with the federal requirement – either because compliance with both is impossible, or because the state requirement stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

Id at 502.

Moreover, the Court continued, the legislative history of the MDA confirms that the MDA

> was not intended to preempt most, let alone all, general common-law duties enforced by damages actions. There is, to the best of our knowledge, nothing in the hearings, Committee Reports, or the debates suggesting that any proponent of the legislation intended a sweeping preemption of traditional common-law remedies against manufacturers and distributors of defective devices.

Id. at 491.

In short, it is abundantly clear that common law remedies which parallel federal requirements are not preempted.[38] *Id.* Even if it may be necessary to prove under state law that those violations were the result of negligent conduct or that they created an unreasonable hazard for users of the product, such requirements are not inconsistent with the federal requirements of the MDA, but rather provide another reason for compliance with existing federal requirements. *Id.*

E. Enlow v. SC Jude Medical Not Applicable

St. Jude relies very heavily on the decision of the federal district judge of the Western District of Kentucky in the case of *Enlow v. St Jude Medical, Inc.*, 171 F.Supp.2d 684 (W.D. Ky. 2001). While supportive of St. Jude's position in this case, it is important to keep in mind that the *Enlow* decision is merely a trial court's ruling on a

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[38] Refer to Appendix B for a table comparison of the type of claims which could be preempted in certain circumstances, compared to the claims raised in this case, which are clearly not subject to preemption.

motion for summary judgment. The case was decided entirely on substantive Kentucky law, and it was never appealed. Moreover, the case has never been cited by any other court as authoritative.

Enlow also clearly conflicts with the decision of the Texas Supreme Court in *Worthy* with respect to Texas substantive law. Although not the picture of clarity, the Kentucky federal trial court appears to hold that preemption should be applied because the product had gone through the PMA process. *Enlow,* 171 F.Supp.2d at 688-89. The Texas Supreme Court in *Worthy,* though, specifically held that the fact alone that the product had gone through the process was not enough:

* * *

are historically state-based and which concern matters of health and safety. *Buckman* held that fraud on the FDA was impliedly preempted because an essential element of the advanced cause of action involved the police powers of the FDA itself. Absent such a contention of fraud on the FDA, there is no authority that a products liability/negligence claim of this sort is subject to implied preemption. Indeed, *Medtronic* continues as the law of the land to the contrary.[48] *See Caraker v. Sandoz Pharmaceuticals Corp.,* 172 F.Supp.2d 1018, 1043 (S.D. Ill. 2001) (citing *Buckman*, 351 U.S. at 353).

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[48] More significant to the resolution of this case than the inapplicable "implied preemption" argument, the *Buckman* Court reaffirmed *Medtronic's* statement of the strong presumption against preemption concerning historic state regulations in matters of health and safety. *Buckman*, 513 U.S. at 350-51.

Conclusion

St. Jude seeks a blanket preemption of all state-based causes of action. According to both the United States and Texas Supreme Courts, there is a strong presumption against the very type of preemption St. Jude seeks here. For the reasons as set out above, St. Jude wholly failed to satisfy its burden to prove preemption should apply. Accordingly. St. Jude's motion for summary judgment should be denied.

Respectfully submitted,

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No. 01-02-00802-CV

IN THE
FIRST DISTRICT COURT OF APPEALS

ESTATE OF JEAN BAKER, DECEASED,

Appellants,

v.

ST. JUDE MEDICAL, S.C., INC., and
ST. JUDE MEDICAL, INC.,

Appellees,

On Appeal, following Severance From Probate Court Number One of Harris County, Texas

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BRIEF FOR APPELLANTS

Oral Argument Requested

* * *

ISSUES PRESENTED

I. WHETHER THE TRIAL COURT ERRED IN GRANTING APPELLEES' OBJECTIONS TO APPELLANTS' CONTROVERTING SUMMARY JUDGMENT EVIDENCE.

II. WHETHER THE MEDICAL DEVICE ACT HAS FULLY OCCUPIED THE FIELD OF MEDICAL DEVICE REGULATION, SUCH THAT EACH STATE COMMON LAW CLAIM ASSERTED BY APPELLANTS PRESENT AN IRRECONCILABLE CONFLICT BETWEEN THE FEDERAL AND STATE STANDARDS OR WHETHER THE IMPOSITION OF

A STATE STANDARD IN A DAMAGE ACTION WOULD FRUSTRATE THE OBJECTIVES OF FEDERAL LAW.

III. WHETHER PREEMPTION APPLIES WHERE APPELLANTS' STATE LAW CLAIMS ARE CONSISTENT WITH THE REQUIREMENTS OF THE MEDICAL DEVICE AMENDMENTS.

IV. WHETHER PREEMPTION APPLIES SINCE THE FDA DETERMINED THAT THE SILZONE-COATED VALVE WAS "ADULTERATED," "MISBRANDED," AND "DEFECTIVE."

V. WHETHER PREEMPTION APPLIES BECAUSE THE FOOD AND DRUG ADMINISTRATION'S CONDITIONAL SUPPLEMENTAL APPROVAL WAS AUTOMATICALLY INVALIDATED WHEN APPELLEES FAILED TO COMPLY WITH MANDATORY CONDITIONS OF APPROVAL.

VI. WHETHER THE ISSUE OF IMPLIED PREEMPTION APPLIES TO THE FACTS IN THIS CASE.

STATEMENT OF FACTS

Ms. Baker died on February 20, 2000 from a paravalvular leak[1] caused by a defective artificial heart valve. (C.R. Vol. V, Part B, pgs. 01415-27). Ms. Baker was

[1] Where silver causes necrosis at the point of suture (the sewing cuff) and as cells die the integrity of the seal between both human tissue and the prosthetic valve is compromised.

surgically implanted with the defective Silzone-coated prosthetic heart valve, manufactured by Appellees,[2] on

[2] Refer to FDA PMA Supplement approval letter, among the attached FDA documents, at pg. 100861-100867. (C.R. Vol. V, Part A, pgs. 01062-68). This document was produced in response to discovery by Appellees and is therefore self-authenticating pursuant to Texas Rule of Civil Procedure 193.7. Tex. R. Civ. P. 193.7. Note also, that there are three groups of FDA documents referred to herein. The documents Bates-stamped numbered beginning with a "1," such as those referenced in this footnote, were produced by Appellees in response to a discovery request. The FDA documents Bates-stamped numbered beginning with either a "00" or a "3," such as those referred to in

* * *

No. 06-0223

In the Supreme Court of Texas

KEITH BAKER, INDIVIDUALLY, AND IAN BAKER, INDIVIDUALLY AND AS INDEPENDENT EXECUTOR OF THE ESTATE OF JEAN BAKER, DECEASED,

PETITIONERS,

VS.

ST. JUDE MEDICAL, S.C., INC., AND ST. JUDE MEDICAL, INC.,

RESPONDENTS.

PETITIONERS' BRIEF ON THE MERITS

On Appeal from No. 01-02-00802-CV
Court of Appeals for the First District of Texas

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* * *

Baker v. St. Jude Medical, S.C., Inc., 178 S. W.3d 127 (Tex.App.-Houston [1st Dist.] 2005, pet. filed). The

participating justices were Chief Justice Radack and Justices Jennings and Higley.

STATEMENT OF JURISDICTION

The Supreme Court has jurisdiction over this appeal because the court of appeals has committed an error of law of such importance to the state's jurisprudence that it should be corrected. Tex. Gov't Code § 22.001(a)(6).

ISSUES PRESENTED

Issue 1: Should claims involving Silzone-coated valves by Texas citizens filing suit in Texas state courts be deemed preempted by federal law when identical claims under the laws of all states have been deemed not preempted in the federal courts?

Issue 2: If the FDA has determined that a product is "defective," "adulterated," "misbranded," and appropriate for an FDA seizure action, are state court civil lawsuits alleging the product is defective somehow nonetheless preempted?

Issue 3: In determining whether FDA approval preempts civil lawsuits, should the courts look at whether the product was FDA-approved when it left the hands of the manufacturer or at the time of judgment in the state court suit?

Issue 4: Does the recent United States Supreme Court opinion in *Bates v. Dow Agrosciences, LLC*, preclude preemption of civil tort suits under the MDA?

Issue 5: Are all medical devices that have ever been PMA- or PMA Supplement-approved by the FDA automatically and forever exempt from all civil liability merely because the FDA approval

implied a (now null and void) finding that the device was "safe," without the necessity of the reviewing court going through the specific approval/allegation analysis mandated by the United States Supreme Court in *Medtronic, Inc. v. Lohr*, and by this Court in *Worthy v. Collagen Corp.*?

Issue 6: Was the now null and void FDA approval of the medical device in dispute, under an abbreviated PMA Supplement application, sufficiently rigorous and specific in its requirements under *Worthy* so as to preempt all civil lawsuits arising from the use of the admittedly defective product?

Issue 7: Can a manufacturing defect claim be dismissed on summary judgment under a claim of federal preemption and without being raised in the summary judgment motion?

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No. 06-1262

FILED
JUN 15 2007
OFFICE OF THE CLERK
SUPREME COURT, U.S.

IN THE

Supreme Court of the United States

KEITH BAKER, Individually, and
IAN BAKER, Individually and as Independent Executor of the Estate of Jean Baker, Deceased,
Petitioners,

v.

ST. JUDE MEDICAL, S.C., INC., and ST. JUDE MEDICAL, INC.,
Respondents.

On Petition for a Writ of Certiorari to the Court of Appeals of Texas, First District, Houston

---

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether, consistent with *Worthy v. Collagen Corp.*, 967 S.W.2d 360 (Tex.), *cert. denied* 524 U.S. 954 (1998), the Texas court of appeals correctly held that 21 U.S.C. § 360k(a) preempts petitioners' state law damages claims involving St. Jude Medical, Inc.'s Class III medical device?

CORPORATE DISCLOSURE STATEMENT

Respondent St. Jude Medical, Inc. is a publicly traded corporation and has no corporate parent. No other publicly held company owns ten percent or more of this respondent's stock.

Respondent St. Jude Medical, S.C., Inc. is a wholly owned subsidiary of St. Jude Medical, Inc. No other publicly held company owns ten percent or more of this respondent's stock.

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IN THE

Supreme Court of the United States

No. 06-1262

KEITH BAKER, Individually, and
IAN BAKER, Individually and as Independent Executor of the Estate of Jean Baker, Deceased,
Petitioners,

v.

ST. JUDE MEDICAL, S.C., INC., and ST. JUDE MEDICAL, INC.,
Respondents.

On Petition for a Writ of Certiorari to the Court of Appeals of Texas, First District, Houston

BRIEF FOR THE RESPONDENTS IN OPPOSITION

Petitioners contend this case presents a good vehicle for the Court to clarify *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), and address two questions: whether, under 21 U.S.C. § 360k(a), FDA premarket approval (PMA) of a Class III medical device preempts conflicting state law claims arising from the device's design, manufacture, and labeling, and whether preemption still holds if that approval is subsequently "lost."

But the reasons for denying certiorari in this case are significant. The primary question presented in the petition is whether medical devices that have lost their FDA approval give rise to preemption. Yet that issue depends on an

assertion—that FDA approval was lost—lacking any support in the record. Throughout this case, petitioners have argued that statements in two documents (the "Dee letter" and the "Fitzgerald memo") conclusively establish that the FDA withdrew approval for the medical device in question. But the Texas probate court excluded those statements, and the Texas court of appeals did not disturb that ruling. Opp'n App. 1a-2a, 8a; Pet. App. 1a, 5a-6a & n.4, 11a n.5 (*Baker v. St. Jude Medical S.C., Inc.*, 178 S.W.3d 127, 132 & n.4, 134 n.5 (Tex. App. 2005)). Instead, as the court of appeals expressly recognized, pursuant to 21 C.F.R. § 814.46, the FDA must follow a formal process to withdraw premarket approval, and it was undisputed "that the FDA never formally withdrew its PMA approval of the valve, and the valve had FDA approval on the date it was implanted." Pet. App. 6a. This discrete and correct evidentiary ruling does not warrant this Court's review, and petitioners' failure to inform this Court of it alone is sufficient reason to deny the petition under Rule 14.4 ("The failure of a petitioner to present with accuracy, brevity, and clarity whatever is essential to ready and adequate understanding of the points requiring consideration is sufficient reason for the Court to deny a petition.").

Moreover, petitioners' assertions of a "conflict" in the relevant preemption authority do not withstand analysis either. In Texas state courts there is no such split. The controlling preemption analysis, set forth in *Worthy v. Collagen Corp.*, 967 S.W.2d 360 (Tex.), *cert. denied* 524 U.S. 954 (1998), was followed by the courts below. More broadly, the overwhelming majority of federal and state cases follow *Worthy*'s analysis. Accordingly, this Court previously has declined to review cases applying preemption principles to Class III medical devices,[1] and there is no reason, as the

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[1] *See, e.g., McMullen v. Medtronic, Inc.*, 126 S. Ct. 1464 (2006); *Knisley v. Medtronic, Inc.*, 126 S. Ct. 420 (2005); *Brooks v. Howmedica*, 535 U.S. 1056 (2002); *Martin* v. *Medtronic, Inc.*, 534 U.S. 1078 (2002);

Solicitor General recently has noted, to depart from that position now. *See* Opp'n App. 34a-35a (Brief for the United States as Amicus Curiae at 2-3, *Riegel v. Medtronic, Inc.*, No. 06-179 (S. Ct. May 2007)).

In sum, the petition presents a unique fact-bound issue that is, in essence, nothing more than a dispute with the probate court's correct evidentiary ruling. Even if one gets beyond the discrete nature of the dispute, the controlling preemption principles are well settled, and there is no material conflict in the law. The asserted bases for this Court's review are not present and the petition should be denied.

STATEMENT OF THE CASE

The Regulatory Bases For Federal Preemption As Applied To Class III Medical Devices

This case involves a question of federal preemption as applied to a Class III medical device. These devices are the most highly regulated and invoke express preemption principles by virtue of the controlling federal regulatory scheme.

In 1976, Congress enacted the Medical Device Amendments (MDA), 21 U.S.C. §§ 360c *et seq.*, to the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 *et seq.*, which vastly expanded the authority of the FDA to regulate medical devices. At the same time it established a comprehensive regulatory regime at the federal level, Congress sought to protect innovations in device technology from being "stifled by unnecessary restrictions." H.R. REP. No. 94-853, at 12 (1976). Specifically, Congress attempted to shield medical devices from the "undu[e] burden[]" imposed by differing state regulation by including in the MDA a "general prohibition on non-Federal regulation." *Id.* at 45. That

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Kemp v. Medtronic, Inc., 534 U.S. 818 (2001); *Worthy v. Collagen Corp.*, 524 U.S. 954 (1998).

general prohibition, which also safeguards the uniformity of the federal regulatory scheme, broadly provides that no State may impose "any requirement" relating to the safety or effectiveness of a medical device that "is different from, or in addition to, any requirement applicable ... to the device" under federal law. 21 U.S.C. § 360k(a).

To obtain premarket approval, manufacturers must provide the FDA with research results and other data supporting the intended use of the device, a sample of the device, and other information, including the proposed device composition and proposed product labeling. Clerk's Record (CR) 3055-56; *see also* 21 U.S.C. § 360c(a)(1)(C); 21 C.F.R. § 814.20(b)). Among other information, a PMA application must include:

- all known reports pertaining to the device's safety and efficacy, § 360e(c)(1)(A);
- a full statement of the components, ingredients, and properties and of the principle or principles of operation of such device, § 360e(c)(1)(B);
- a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device, § 360e(c)(1)(C);
- samples of the device when practical, § 360e(c)(1)(E); and
- specimens of the labeling proposed to be used for the device, § 360e(c)(1)(F).

CR 3055-56.

Device innovations also receive this same scrutiny. Thus, if a PMA medical device is subsequently modified, the manufacturer must seek approval for the modification through the "PMA supplement" process. CR 3056; *see also* 21 U.S.C. § 360e(d)(6)(A)(i); 21 C.F.R. § 814.39. All the procedures and actions applicable to a PMA application apply to a PMA

supplement. CR 2791-92 (citing *Worthy*, 967 S.W.2d at 364-65 (describing the PMA supplement process) and *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 222 (6th Cir. 2000) (same)). In a PMA supplement, the manufacturer must provide the same information required by a PMA application to support approval of the proposed modifications. CR 3056-57; *see also* 21 C.F.R. § 814.39(c).

PMA and PMA supplement submissions are voluminous, and the FDA's experts evaluate them fully. On average, the FDA spends 1200 hours reviewing a PMA. CR 3056; *see generally Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344-45 (2001) (describing the PMA process); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 911 (7th Cir. 1997) (same). When the medical device at issue is a heart valve, the FDA employs a staff of experts in that specific area, and uses standards contained in an FDA document entitled "Replacement Heart Valve Guidance" (Guidance Document).[2] CR 3059.

The medical device at issue in this case was reviewed through these processes. In December 1982, following two years of regulatory review, the FDA approved St. Jude Medical's initial PMA application for a mechanical heart valve, called the "Bi-Leaflet Center Opening Pyrolytic Carbon Cardiac Valve." CR 3161-62. In the years following approval, St. Jude Medical provided the FDA with a tremendous amount of additional data regarding the safety and efficacy of the valves, in a series of PMA supplements. *Id.*

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[2] The Guidance Document sets forth the type of testing that must be conducted, and the test data that must be submitted, to adequately demonstrate heart valve safety and efficacy in any PMA or PMA supplement application for that type of device. *See* CR 3059. If the manufacturer deviates from the recommended tests and other recommendations, it must demonstrate the equivalency or superiority of its choice of alternative to the satisfaction of the FDA or the FDA will refuse approval. *Id.*

This standard mechanical heart valve achieved wide acceptance. As medical research continued to evolve, however, St. Jude Medical developed innovative new technologies for physicians and their patients, including modifying its heart valve to incorporate a rotating sewing cuff that eliminated the need for surgeons to position the valve prior to suturing. CR 3162. The PMA supplement for this modification, known as the Masters Series valve, was supported by extensive documentation, including proposed labels, design specifications, and manufacturing standards, and the FDA approved it. CR 3162-63.

Over time, it became clear that an additional new technology was needed to address a well-known risk associated with artificial heart valves: endocarditis. CR 3156. Even with aggressive treatment, endocarditis can be life-threatening, causing death in 25% to 60% of cases. *Id.*

Silver, in various forms, has been used as an antimicrobial agent for many years, including as an infection-resistant coating for other medical devices. CR 3157, 3222, 3237. Spire Corporation had developed a patented technology to coat biomaterials with a silver coating several microns thick, subjected the coating to numerous safety and efficacy in vitro (laboratory) and in vivo (patient or animal) tests, and successfully used it on several medical devices. CR 3285-86. Thus, in December 1995, St. Jude Medical preliminarily notified the FDA of its plan to modify its Masters Series valve to incorporate Spire's infection-resistant, sterile silver coating on the sewing cuff. CR 3148, 3163-64, 3285.

The FDA advised St. Jude Medical that its proposed plan required numerous modifications—based in part on the heart valve Guidance Document—including performance of specific tests and submission of additional data and information. CR 3164-65. Almost a year and a half later, in May 1997, after it had compiled the data the FDA specified, St. Jude Medical formally submitted its PMA supplement to add the

silver coating (under the name Silzone®) to the sewing cuff on its Masters Series mechanical heart valve. CR 3165-67.[3]

The FDA's review of the formal PMA supplement took more than 10 months to complete, in addition to the many months the FDA already had spent reviewing St. Jude Medical's preliminary proposal. CR 3167. During this review process, the FDA demanded further testing and data, label changes, and manufacturing changes. CR 3167-70.

In March 1998, the FDA finally approved the PMA supplement, concluding there was sufficient evidence that the Masters Series heart valve with a Silzone®-coated sewing ring was reasonably safe and effective for its intended use. CR 3170-72. Through its approval, the FDA required St. Jude Medical to use the exact design, labeling, and manufacturing process it had approved. *Id.* The FDA also prohibited St. Jude Medical from making claims regarding efficacy of the Silzone® coating in preventing endocarditis pending the completion of further testing. *Id.*

St. Jude Medical thereafter manufactured and marketed the Silzone® valve in conformity with the established requirements. CR 3152, 3173. Petitioners have never adduced any evidence that the specific valve at issue in this case deviated from the FDA-required design, label, or manufacturing process.

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[3] This application provided important safety and efficacy data regarding the proposed silver coating material, design specifications, a sample package label for the new valve, and details regarding the manufacturing process that would be employed. *See* CR 3165-67. It also included a peer-reviewed report on a human clinical trial of the Silzone® valve. CR 3173-74, 3236. In addition, Spire had submitted to the FDA its own Master File in support of its patented silver coating with additional information on the coating process, quality control procedures, and the results of its own tests, and St. Jude Medical's PMA supplement relied on these materials as well. CR 3166, 3286.

Concomitantly with the marketing of the valve, St. Jude Medical continued to study its efficacy. The largest and most comprehensive of these studies was the Artificial Valve Endocarditis Reduction Trial (AVERT). CR 3176. An independent data safety and monitoring board (DSMB) periodically reviewed data generated by the AVERT. CR 3176. On January 21, 2000, the DSMB concluded the preliminary data from AVERT indicated that a very small percentage of the patients with the Silzone® valve had an equally small, but statistically significant, increased incidence of explant due to paravalvular leak. CR 3177-78. That same day, St. Jude Medical began a voluntary world-wide recall of all unimplanted Silzone® products.[4] *Id.*

Following St. Jude Medical's voluntary recall, the FDA audited the company but never recommended any change to the company's voluntary recall plan or took formal regulatory action. CR 535-40 ("Current inspection was prompted by a voluntary recall of all unimplanted heart valves with silver ion (silzone) impregnated sewing cuffs . . . . No FDA 483 was issued to this firm. It appears that St. Jude responded quickly to the outcomes of the [redacted] study"); CR 3178. The FDA also never took any of the steps needed to formally revoke approval for the Silzone® valve described in 21 C.F.R. § 814.46. Two FDA officials wrote statements, referred to in this case as the "Dee letter" and "Fitzgerald memo," indicating the company's action met "the formal definition of a 'Recall'" and was in lieu of FDA "legal action to remove the defective products from the market." Pet. App. 38a; *see also* Pet. App. 5a-6a. At the same time, the FDA's position on

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[4] In connection with this voluntary recall effort, St. Jude Medical alerted the FDA and also sent overnight alert letters to those cardiac surgeons and other physicians known to use its products. CR 3177-78; *see also* CR 1334-43. Those letters asked the recipients to stop using the Silzone® valve and to return any unimplanted Silzone® products. CR 3177-78; *see also* CR 1334-43.

already-implanted valves was that normal monitoring was sufficient to detect the relatively low-risk occurrence reported in the AVERT study. CR 604, 619-23.

Petitioners Keith Baker and Ian Baker filed a lawsuit in Probate Court Number One of Harris County, Texas claiming that their mother's death resulted from negligent care provided by her physicians. CR 925. They also alleged several common law product liability theories and a statutory deceptive trade practices claim (Tex. Bus. & Com. Code Ann. § 17.01 *et seq.* (Vernon 2002 & Supp. 2006)) against St. Jude Medical. CR 946-48. Each of petitioners' claims alleged the heart valve is "an unreasonably dangerous and defective" medical device that should have been manufactured and marketed with a design and label different from the one the FDA approved and required St. Jude Medical to use. *See* CR 947.

St. Jude Medical moved for summary judgment arguing that both express and implied preemption barred the common law and statutory claims. CR 2788-2812. Because the record established the requisite PMA and PMA supplement approval of the Silzone®-coated sewing cuff (CR 1019-1048), the probate court granted summary judgment (Pet. App. 21a). It also upheld several of St. Jude Medical's evidentiary objections and excluded the salient portions of the Dee letter (Pet. App. 37a-41a), and the Fitzgerald memo (Pet. App. 33a-36a). Opp'n App. 1a-2a, 8a. The probate court later denied petitioners' new trial motion and renewed evidentiary arguments. CR 4362.

Afterward, St. Jude Medical also successfully moved for summary judgment on the claims of an additional 69 plaintiffs in a coordinated state court proceeding in Harris County, Texas involving the same Silzone® heart valve. *See* Opp'n App. 9a, 21a-24a (*In re Heart Valve Litigation*, 2005 WL 1541059 (Tex. App. June 30, 2005)).

Petitioners in this case then appealed (CR 4363), and the 69 plaintiffs in the coordinated Texas proceeding filed a companion appeal. The court of appeals affirmed summary judgment both in this case and in the companion appeal, and published its decision in this case. Pet. App. 1a-20a; Opp'n App. 9a-24a. It did not disturb the probate court's exclusion of the Dee letter (Pet. App. 37a-41a), or the Fitzgerald memo (Pet. App. 33a-36a) excerpts. *See* Pet. App. 5a-6a & n.4. It also affirmed on both express and implied preemption grounds. *See id.* at 16a-17a (affirming judgment for St. Jude Medical on negligence, product liability and Texas Deceptive Trade Practices Act claims on express preemption grounds); *id.* at 17a-20a (affirming judgment for St. Jude Medical on fraud claim on implied preemption grounds).

In affirming, the court of appeals expressly recognized that, pursuant to 21 C.F.R. § 814.46, the FDA must follow a formal process to withdraw premarket approval, and that it was undisputed "that the FDA never formally withdrew its PMA approval of the valve, and the valve had FDA approval on the date it was implanted in Baker." Pet. App. at 6a.

The court of appeals denied petitioners' motion for rehearing on February 8, 2006. Opp'n App. 25a-26a. Petitioners here then sought discretionary review by the Texas Supreme Court, although the 69 plaintiffs in *In re Heart Valve Litigation* did not. After the parties filed merits briefs, the Texas Supreme Court denied review in this case on December 15, 2006. Pet. App. 22a.[5]

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[5] In one place, the petition states that "[t]hese issues were appealed directly by the petitioners to the Texas Supreme Court." Pet. 5. But in fact the Texas Supreme Court denied petitioners' discretionary petition for review after full merits briefing on issues such as whether the court of appeals' opinion in this case was a faithful application of the Texas Supreme Court's precedent, *Worthy*, 967 S.W.2d 360. *See* Pet. App. 22a, 110a-112a.

REASONS FOR DENYING THE PETITION

A. The Petition Incorrectly Represents The Record Regarding The Status Of FDA Approval For The Medical Device In Question

The federal regulations provide one avenue by which the FDA may withdraw premarket approval: it must issue formal notice to the medical device manufacturer, hold a hearing, and offer an appeal process. *See* 21 C.F.R. § 814.46. The Texas court of appeals recognized no such steps were taken for the Silzone® device, and thus it was undisputed "that the FDA never formally withdrew its PMA approval of the valve, and the valve had FDA approval on the date it was implanted in Baker." Pet. App. 6a; *cf.* Opp'n App. 44a (Solicitor General's amicus brief in *Riegel*, describing statutory requirements for FDA to withdraw premarket approval and stating "[w]here the FDA has not taken such action, its approval of the PMA – and the 'requirements' that result from that approval – remain in effect.").

At best, the petition mischaracterizes the appellate court's statement that it was undisputed the FDA never formally withdrew approval. It represents in one place that the Texas court of appeals merely "implied that the Silzone-coated valves must still be FDA-approved" and suggests it was "clearly . . . incorrect" in reaching that conclusion. Pet. 10.

More often, however, the petition represents this case as unequivocally involving the opposite circumstance – that the Silzone® valve undisputedly lost approval – without any acknowledgement of the probate court's contrary evidentiary finding. *See* Pet. 1 ("suppose a particular device is no longer FDA-approved?"); 12 ("Preemption When the Product is No Longer FDA-Approved" and "this product is no longer approved by the FDA"); 13 ("the product no longer has FDA approval").

To make these assertions, petitioners construct an argument based upon the Dee letter and Fitzgerald memo (Pet. 9-11), yet never once acknowledge that those documents were excluded by the probate court, or that their exclusion was left undisturbed by the Texas court of appeals (Pet. App. 5a-6a & n.4, 11a n.5). This omission is not a minor one, given that half the petition is premised on the Dee letter and Fitzgerald memo and results in petitioners' argument that certiorari is warranted because the lower courts upheld preemption for a device that was not FDA-approved.

There is no reason for this Court to grant certiorari to address a putative legal issue not supported by the record in this case. *See* S. Ct. R. 14.4 ("The failure of a petitioner to present with accuracy, brevity, and clarity whatever is essential to ready and adequate understanding of the points requiring consideration is sufficient reason for the Court to deny a petition."). There also is no reason for this Court to grant certiorari to address the propriety of the probate court's evidentiary ruling. *See* S. Ct. R. 10 ("A petition for a writ of certiorari is rarely granted when the asserted error consists of erroneous factual findings.").

B. There Is No Split Of Authority Regarding Preemption Involving Medical Devices That Allegedly Lost FDA Approval After Implantation

Even without petitioners' fundamental record problem, the grounds for denying certiorari are ample. According to petitioners, the "opinion of the Texas Court of Appeals is the only published appellate opinion in this country in which a court has directly addressed" the issue of whether preemption applies when a "product is no longer approved by the FDA." Pet. 12. On its face, this question presents no split in authority that can traditionally provide a "compelling reason" under Rule 10 for review.

The vast majority of courts—and *all* recent appellate decisions—have found that premarket approval and the resultant bar on changes to an FDA-approved device create specific federal requirements that preempt conflicting state common law damages actions. *See, e.g.*, Pet. App. 11a-16a; *Riegel v. Medtronic Corp.*, 451 F.3d 104 (2d Cir. 2006); *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 487–88 (7th Cir. 2005); *Cupek v. Medtronic, Inc.*, 405 F.3d 421, 424 (6th Cir. 2005); *Horn v. Thoratec Corp.*, 376 F.3d 163, 171–73 (3d Cir. 2004); *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 799 (8th Cir. 2001) (en banc); *Martin v. Medtronic, Inc.*, 254 F.3d 573, 585 (5th Cir. 2001); *Kemp*, 231 F.3d at 226–27 (6th Cir.); *Mitchell*, 126 F.3d at 911 (7th Cir.); *Worthy*, 967 S.W.2d at 376 (Tex.); *Fry v. Allergan Med. Optics*, 695 A.2d 511, 516 (R.I. 1997); *Green v. Dolsky*, 685 A.2d 110, 117 (Pa. 1996).

In contrast to these decisions, petitioners identify (at Pet. 1) – but never discuss – an outdated federal court of appeals decision that did not find premarket approval to be preemptive—*Goodlin* v. *Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999). The decision in *Goodlin*, which arises on facts different from those presented here, is not reflective of the current state of law and is no threat to the stability of the prevailing authority in the Texas state courts or elsewhere.[6]

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[6] Petitioners also identify one unpublished interlocutory district court order that involved the same medical device as this case and did not find the PMA and PMA supplement process preemptive, *In re St. Jude Medical, Inc., Silzone Heart Valves Prods. Liab. Lit.*, 2004 U.S. Dist. LEXIS 148 (D. Minn. Jan. 5, 2004) (MDL No. 01-1396). (Pet. App. 42a, 77a). But they do not contend that this order is of any significance in terms of a split of authority (Pet. 7-10), nor could they given the order's interlocutory nature and the fact it is only a trial court order that has not yet received appellate review. *See* S. Ct. R. 10 (identifying other compelling circumstances where review is warranted).

In the eight years since *Goodlin* was decided, no other court of appeals and no other state supreme court has joined the Eleventh Circuit. Given the legal and administrative developments in the meantime, there is reason to believe that the Eleventh Circuit will correct itself. *See* Opp'n App. 51a-52a.

The appellate court's decision in this case also does not conflict with this Court's precedent *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005). Petitioners argue that "it is not entirely clear" after *Bates* "when requirements might be deemed imposed by state court suits so as to run afoul of preemption provisions." Pet. 25. But once again, the vast majority of lower courts, and *all* courts to have considered the issue recently, have held that, under the MDA, state tort claims can be preempted. *See, e.g.*, Pet. App. 7a-11a; *McMullen*, 421 F.3d at 487; *Cupek*, 405 F.3d at 424; *Horn*, 376 F.3d at 173–77; *Brooks*, 273 F.3d at 799; *Martin*, 254 F.3d at 584; *Kemp*, 231 F.3d at 224; *Mitchell*, 126 F.3d at 913–14; *Papike v. Tambrands Inc.*, 107 F.3d 737, 741 (9th Cir. 1997); *Worthy*, 967 S.W.2d at 376–77; *Fry*, 695 A.2d at 517; *Green*, 685 A.2d at 117–18.

Similarly, petitioners contend that "*Bates* made one point abundantly clear: even if a jury verdict in a damages claim were to be based on a finding that would conflict with an agency finding, the verdict would never support application of the preemption doctrine." Pet. 25. But in *Bates*, this Court held that the term "requirements" in the identically-worded Federal Insecticide, Fungicide, and Rodenticide Act includes common law claims. *Bates*, 544 U.S. at 443. This issue thus is also well settled.[7] *See* Opp'n App. 44a-45a (Solicitor

[7] As the FDA explained through the Solicitor General, during the PMA process it conducts "a thorough review of a substantial scientific record" (Brief for the United States as Amicus Curiae, *Horn v. Thoratec*, 2004 WL 1143720, at *16 (3d Cir. May 14, 2007) (No. 02-4597)) and performs a "careful balancing" of the benefits and risks associated with a particular

General acknowledging that this Court has consistently held state common law actions can create state "requirements").

Whatever petitioners' confusion about the state requirement side of the preemption analysis, it is not reflected in any recent circuit or state high court decision. There also is no conflict between the appellate court's position and this Court's *Bates* decision. The result reached below likewise comports with the prevailing administrative construction of the pertinent regulatory scheme. Finally, as the FDA has emphasized, "very strong public policy considerations" support application of preemption principles to state common law claims involving Class III medical devices. Brief for the United States as Amicus Curiae, *Horn v. Thoratec*, 2004 WL 1143720, at *25 (3d Cir. May 14, 2007) (No. 02-4597). According to the FDA—the agency charged with implementing the MDA—"the accomplishment of its regulatory goals would be undermined if lay judges or juries were permitted to second-guess the scientific judgments it makes in approving a PMA application." Opp'n App. 45a.

CONCLUSION

The petition at bottom asks this Court to revive and resolve a state law evidentiary dispute that does not present a reason to grant certiorari and was not preserved for appeal. Beyond that, it asks this Court to set a Texas court on its proper course without any showing that the preemption principles applied are in need of correction. Even as to the result reached, an examination of the recent and controlling case

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device (*id.* at *29). State tort actions, however, usurp "the central role of [the] FDA" by requiring "lay judges and juries to second-guess the balancing of benefits and risks of a specific device." *Id.* at *25. Because such second-guessing "may disrupt the careful balancing performed by the FDA in the PMA process" (*id.* at *29), state common law claims such as those asserted in *Horn*—and here—"are preempted under federal law." *Id.* at *31.

law reveals no material conflict in the application of established preemption principles to this unique set of facts. For each of these reasons, the petition should be denied.

Respectfully submitted,

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Dated: June 15, 2007

APPENDIX

APPENDIX A

ESTATE OF JEAN BAKER DECEASED

312543-402

IN THE PROBATE COURT NUMBER ONE (1) OF
HARRIS COUNTY, TEXAS

ORDER SUSTAINING OBJECTIONS TO
SUMMARY JUDGMENT EVIDENCE

On this day came on for consideration St. Jude Medical's Objections to and Motion to Strike Plaintiffs' Summary Judgment Evidence, and the Court having reviewed the plaintiffs' Motion for Partial Summary Judgment, St. Jude Medical's objections, and the plaintiffs' response thereto, decided to grant the motion. It is therefore ORDERED that St. Jude Medical's objections to the following summary judgment evidence submitted by plaintiffs in support of their motion for partial summary judgment are hereby sustained, and the following summary judgment evidence is stricken from the record:

~~1. The recall letters sent by St. Jude Medical to its customers (Exhibit B to Plaintiffs' Motion at pages 001374-001380~~; RA

2. The following statements contained in the letter written on March 22, 2000 by Edwin S. Dee to Terry Shepherd, which is part of Exhibit B to plaintiffs' motion at pages 001367-001369:

> "The use of the mechanical heart valves having cuffs with Silzone® Coating has been associated with a statically-higher rate of paravalvular leaks, and with a significantly higher rate of explant due to the endorcarditis.

> We have reviewed your action and conclude that it meets the formal definition of a "Recall". This is significant, as your action is an alternative to a Food and Drug Administration legal action to remove the defective products from the market."

3. The following statements contained in an FDA internal memorandum dated March 20, 2000 from Mary Ann Fitzgerald to Derk J. Mauw, which is a part of Exhibit C to plaintiffs' motion at pages 300219-300221:

> "We consider the devices to be adulterated and misbranded because there is a statically significantly higher rate of paravalvular leaks with the silver ion (Silzone®) coated sewing cuffs leading to valve explants. The device defects presents a moderate risk of adverse health consequences."

Signed this 29th day of April, 2002.

/s/ Russell P. Austin
HON. RUSSELL P. AUSTIN

APPENDIX B

ESTATE OF JEAN BAKER DECEASED

312543-402

IN THE PROBATE COURT NUMBER ONE (1)
OF HARRIS COUNTY, TEXAS

ORDER

Came on for consideration on this date, St. Jude Medical's objections to the controverting evidence offered by plaintiffs in support of their Response to St. Jude Medical's Motion for Summary Judgment. The Court, after consideration of the objections, hereby ORDERS that the objections are granted or denied as reflected below:

APPENDIX "A"

Granted ✓ Denied _

APPENDIX "B"

Granted ✓ Denied _

AFFIDAVIT OF NEIL VAN HOOYDONK

Page 3, Paragraph 1

The affiant states: "In November 1999, the product was subject to a recall in the United Kingdom for an unexpected incidence of thrombi associated with the use of the product."

Granted _ Denied ✓

Page 3, Paragraph 1

The affiant states: "In addition, an unexpected incidence of paravalvular leaks associated with the product were reported by November 1999 through early Jan 2000."

Granted _ Denied ✓

Page 3, Paragraph 2

The affiant states: "St. Jude was required, as a condition of the PMA Supplement approval, to report these events to the FDA within 5 or 10 days of 'becoming aware' of same. The FDA file does not reflect such notification was timely provided, thus effectuating the automatic invalidation of the PMA Supplement approval pursuant to its express terms."

Granted ✓ Denied _

Page 3, Paragraph 3

The affiant states: "On March 20, 2000, the FDA made a determination that the Silzone® coated St. Jude values as "adulterated" and "misbranded." [site]

Granted ✓ Denied _

Page 3, Paragraph 3

The affiant states: "Two days later, on March 22, 2000, the FDA sent St. Jude a letter advising that the FDA agreed with the voluntary recall, and that it was considered to be in lieu of an FDA action to mandate the immediate withdrawal of the products, which the FDA now considered 'defective,' from the market"

Granted ✓ Denied _

Page 3, Paragraph 4

The affiant states: "Thus, once the FDA made a determination that the product as 'adulterated,' 'misbranded,' and 'defective,' [sic] St. Jude no longer had authorization under any PMA Supplement approval to manufacture, sell, market, or distribute the product with Silzone® coating."

Granted ✓ Denied _

Page 3, Paragraph 5

The affiant states: "The PMA Supplement approval is closer in many aspects some ways to the 510(k) process than the full PMA process. [sic] In this case, the PMA Supplement approval for the subject valve with Silzone coating is more similar to the least stringent approval process, the 510k [sic] process, than the full PMA process."

Granted _ Denied ✓

Page 5, Paragraph 1

The affiant states: "Not absolutely required since 1997, the FDA nonetheless invariably does require, with a full PMA application, that the product be submitted for consideration to an independently appointed Review Committee. . . . This is a very important part of insuring the safety of the device in the FDA approval process."

Granted _ Denied ✓

Pages 6-7, Paragraphs 1 and 3

The affiant states: "Prior to submission of a PMA application to the agency and the Review Committee (where applicable), human clinical studies must be performed

under an approved Investigational Device Exemption (IDE) and the supervision of an Investigational Review Board . . . . The results of the human clinical trials are then submitted and carefully reviewed by both the FDA, and where applicable, the Review Committee. If, after all this study and observation of the product, the FDA determines that the product is both safe and effective, it is approved for marketing under the conditions set by the FDA."

Granted _ Denied ✓

Page 7, Paragraphs 2-6

The affiant gives a lengthy explanation of the 510(k) process.

Granted _ Denied ✓

Page 8, Paragraph 1

The affiant states: "In many respects, the typical PMA Supplement process is much more similar to the 510(k) process than the full PMA process. For example, a PMA Supplement application is often a very abbreviated package, nowhere near the volume of a full PMA application. In addition, rarely is an Independent Review Committee appointed to review a PMA Supplement application. Finally, rarely is the manufacturer required to subject a product to human clinical trials in a PMA Supplement application."

Granted _ Denied ✓

Page 8, Paragraph 2

The affiant states: "The PMA Supplement Application for the subject valves reflects nowhere near the rigorous process that would be required for the full PMA ap-

proval. This is evidenced by the fact that the original PMA application consists of three file boxes of documentation and the supplement is about two inches thick. A full PMA application would certainly be larger than what was submitted in this case for the subject "valves."

Granted ✓ Denied _

Page 8, Paragraph 3

The affiant states: "If the agency had elected to submit this supplement to a review committee, it is my opinion that the review committee would have recommended disapproval of the application until such time that clinical trials had been performed establishing reasonable assurance of safety and effectiveness."

Granted _ Denied ✓

Page 9, Paragraph 2

The affiant states: "If SJM had followed the FDA guidelines there is a reasonable probability that evidence of bio-incompatibility would have been identified."

Granted ✓ Denied _

Page 9, Paragraph 3

The affiant states: "In my expert opinion, a PMA Supplement application for a design change is not as rigorous in as a full PMA application." [sic]

Granted _ Denied ✓

Page 9, Paragraph 4

The affiant states: "In this case for the subject valves, for the reasons as set out above, the PMA Supplement

application was not as rigorous as it would have been had the modified product gone through the full PMA process. Moreover, the review of the safety and efficacy of the proposed change by the FDA was not nearly as thorough and rigorous as it would have been had the product been submitted to a full PMA approval. Due to the: (a) short application; (b) complete absence of clinical human studies; (c) complete absence of Advisory Committee review and oversights; and (d) shortcut animal studies; it is my expert opinion that the PMA Supplement process in this case was neither rigorous nor thorough, and that it was much closer to a 510(k) approval than a full PMA approval."

Granted _ Denied ✓

FDA DOCUMENTS

a. March 20, 2000. Letter from Edwin S. Dee (the "Dee letter")

Granted ✓ to the extent of Order Sustaining Objection to S/J Evidence Denied _

b. March 22, 2000. Memorandum from Mary Ann Fitzgerald (the "Fitzgerald memo")

Granted ✓ to the extent of Order Sustaining Objection to S/J Evidence Denied _

Signed this 29th day of April, 2002.

/s/ Russell P. Austin
HON. RUSSELL P. AUSTIN

APPENDIX C

COURT OF APPEALS OF TEXAS,
HOUSTON (1ST DIST.)

(Cite as: 2005 WL 1541059 (Tex.App.-Hous. (1 Dist.)))

In re HEART VALVE LITIGATION

HOWARD BOYLE,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

LAVERNE BROWN,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

SAUNAIE BROWN,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

JACK CALHOUN,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

ARTURO CARDENAS,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

NEIL CHANDLER,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

RONALD COOPER,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

DANIEL DIXON,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

MARY JANETTE DOWELL,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

GLORIA EVERITT,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

ELIDA FLORES,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

ROBERT FOLTZ,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

EARL FUTRELLE,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

CAROLYN GIBBENS,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

RICHARD GILBERT,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

CLIFFORD HAMILTON,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

EDGAR HENDERSON,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

LINWOOD HEBERT,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee,

FRANCIS HITESHEW,

Appellant.

v.

ST. JUDE MEDICAL, INC.,

Appellee.

THOMAS HOVANEC,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

STEVEN HUGGHINS,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

JAMES IVIE,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

DAMON KOEN,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

FRAN LANE,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

WILLIAM LEWELLYN,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

GLADYS LIPSCOMB,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

ROBERT LOPEZ,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

BEULAH MALINA,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

MARIO MARTINEZ,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

RAMIRO MARTINEZ,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

JANIE MCDANIEL,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

PHILIP MEUSER,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

JAVIER MUNOZ,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

TONY NAVARRO,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

HUMBERTO NUNEZ,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

MARY ONESTY,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

BELINDA PEREZ,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

WESLEY PERREN,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

GERALD PETSCH,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

SANDELLA PHILLIPS,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

JOHNNEY POLLAN,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

OSCAR RAMIREZ,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

LILLIE REED,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

FRANK RIOS,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

PETRA RODRIGUEZ,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

HENRY ROTHSCHILD,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

EARL SADLER,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

DAVID V. SALAS,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

SYLVIA SANCHEZ,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

LEE A. SIAS, VERNELL SIAS, WILLIAM CRON, NORMAN HAUGEN, GLENDA BREWER, JARVIS CHRISTIAN, BILLY BAKER, RONNIE KING, JANET KING, DONALD IRVIN, SANDRA K. SAM, AND KENNETH E. KANTOROWICZ,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

MARTIN SOUTHWICK,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

JOHN STARK,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

ROGER STEWART,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

ROBERT STROBEL,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

MOLLY TAPIA,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

JOSE R. VALENTIN,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

OLA MAE WILLIAMS,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

ELIANA ZADIK,

Appellant,

v.

ST. JUDE MEDICAL, INC.,

Appellee.

Nos. 01-03-00198-CV, 01-04-00291-CV, 01-04-00292-CV, 01-04-00293-CV, 01-04-00294-CV, 01-04-00295-CV, 01-04-00296-CV, 01-04-00297-CV, 01-04-00298-CV, 01- 04-00299-CV, 01-04-00300-CV, 01-04-00301-CV, 01-04-00302-CV, 01-04-00303-CV, 01-04-00304-CV, 01-04-00305-CV, 01-04-00306-CV, 01-04-00307-CV, 01-04-00308-CV, 01-04-00309-CV, 01-04-00310-CV, 01-04-00311-CV, 01-04-00312-CV, 01-04-00313-CV, 01-04-00314-CV, 01-04-00315-CV, 01-04-00316-CV, 01-04-00317-CV, 01-04-00318-CV, 01-04-00319-CV, 01-04-00320-CV, 01-04-00321-CV, 01-04-00322-CV, 01-04-00323-CV, 01-04-00324-CV, 01-04-00325-CV, 01-04-00326-CV, 01-04-00327-CV, 01-04-00328-CV, 01-04-00329-CV, 01-04-00330-CV, 01-04-00331-CV, 01-04-00332-CV, 01-04-00333-CV, 01-04-00334-CV, 01-04-00335-CV, 01-04-00336-CV, 01-04-00337-CV, 01-04-00338-CV, 01-04-00339-CV, 01-04-00340-CV, 01-04-00341-CV, 01-04-00342-CV, 01-04-00343-CV, 01-04-00344-CV, 01-04-00345-CV, 01-04-00346-CV, 01-04-00347-CV.

June 30, 2005

On Appeal from the 215th District Court, Harris County, Texas, Trial Court Master Cause Nos.2002-27580-A, 2002-02993-A, 2002-02970-A.

On Appeal from the 113th District Court, Harris County, Texas, Trial Court Cause No.2002-26969-A.

On Appeal from the 127th District Court, Harris County, Texas, Trial Court Cause

Nos.2002-02865-A, 2002-02966-A, 2002-02977-A, 2002-02979-A, 2002- 02978-A.

On Appeal from the 125th District Court, Harris County, Texas, Trial Court Cause Nos.2002-02867-A, 2002-02982-A.

On Appeal from the 295th District Court, Harris County, Texas, Trial Court Cause Nos.2002-02981-A, 2002-42469-A, 2002-02994-A, 2002-26965-A.

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On Appeal from the 269th District Court, Harris County, Texas, Trial Court Cause Nos.2002-26968-A, 2002-02972-A, 2002-02869-A.

On Appeal from the 334th District Court, Harris County, Texas, Trial Court Cause Nos.2002-26961-A, 2002-02961-A.

On Appeal from the 333rd District Court, Harris County, Texas, Trial Court Cause Nos.2002-26962-A, 2002-02992-A, 2002-55917-A.

On Appeal from the 61st District Court, Harris County, Texas, Trial Court Cause Nos.2002-26970-A, 2002-42468-A.

On Appeal from the 152nd District Court, Harris County, Texas, Trial Court Cause Nos.2002-02987-A, 2002-02962-A, 2002-26963-A.

On Appeal from the 133rd District Court, Harris County, Texas, Trial Court Cause Nos.2002-02964-A, 2002-02968-A.

On Appeal from the 55th District Court, Harris County, Texas, Trial Court Cause Nos.2002-26967-A, 2002-02871-A, 2002-42470-A, 2002-02973-A.

On Appeal from the 129th District Court, Harris County, Texas, Trial Court Cause Nos.2002-02975-A, 2002-02872-A, 2002-02960-A.

On Appeal from the 280th District Court, Harris County, Texas, Trial Court Cause Nos.2002-02991-A, 2002-02863-A.

On Appeal from the 281st District Court, Harris County, Texas, Trial Court Cause Nos.2002-02870-A, 2002-02980-A.

On Appeal from the 157th District Court, Harris County, Texas, Trial Court Cause Nos.2002-02866-A, 2002-02652-A.

On Appeal from the 1 1 th District Court, Harris County, Texas, Trial Court Cause Nos.2002-02965-A, 2002-02971-A.

On Appeal from the 80th District Court, Harris County, Texas, Trial Court Cause No.2002-03213-A.

On Appeal from the 151st District Court, Harris County, Texas, Trial Court Cause Nos.2002-02969-A, 2002-026966-A, 2002-02986-A, 2002-02959-A.

On Appeal from the 165th District Court, Harris County, Texas, Trial Court Cause No.2002-02967-A.

On Appeal from the 234th District Court, Harris County, Texas, Trial Court Cause Nos.2002-02985-A, 2002-26959-A.

On Appeal from the 164th District Court, Harris County, Texas, Trial Court Cause No.2002-46754-A.

On Appeal from the 189th District Court, Harris County, Texas, Trial Court Cause No.2002-02990-A.

On Appeal from the 190th District Court, Harris County, Texas, Trial Court Cause No.2002-02868-A.

MEMORANDUM OPINION

SHERRY RADACK, *Chief Justice.*

The plaintiffs in these appeals were implanted with allegedly defective heart valves, which were manufactured by St. Jude Medical, Inc. (St. Jude) and Spire Corporation (Spire). St. Jude and Spire filed motions for summary judgment, in which they contended that plaintiffs' claims were preempted by their compliance with the Food and Drug Adminis-

trations's pre-market approval procedures for certain medical devices. The trial court granted the manufacturers' motions for summary judgment and these appeals followed. We affirm.

Factual Background

In 1982, the FDA approved St. Jude's initial PMA application for a mechanical heart valve. During the following years, St. Jude made several improvements to the valve, which were also approved through a series of PMA supplements. One of these improvements was the incorporation of a rotating sewing cuff, which eliminated the need for surgeons to position the valve before sewing it in place.

In an effort to combat endocarditis, a life-threatening infection of the heart muscle, St. Jude notified the FDA that it planned to develop a mechanical heart valve with an infection-resistant, sterile, silver coating on the sewing cuff. St. Jude contracted with Spire to use Spire's patented ion beam assisted deposition process to apply a thin silver coating to St. Jude's heart valves. In May 1997, after an FDA-required animal test was completed, St. Jude submitted a PMA supplement to add the Silzone[1] coating to its already approved heart valve.

In March 1998, the FDA approved St. Jude's PMA supplement. As a part of its approval, the FDA imposed several post-approval requirements, including how the valve could be marketed. Specifically, the FDA prohibited St. Jude from making any claims about the efficacy of the Silzone coating in preventing endocarditis. St. Jude began marketing the Silzone valve accordingly.

St. Jude, however, continued to participate in studies to determine the efficacy of the Silzone coating in preventing

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[1] Silzone® is the trademark name for the sterile, silver coating that St. Jude added to the sewing cuff of its heart valve.

endocarditis. One of these studies was the Artificial Valve Endocarditis Reduction Trial (AVERT). On January 21, 2000, an independent board reviewing the AVERT data concluded that patients with the Silzone valve were more likely to experience a post-operative complication, known as a paravalvular leak. Approximately 2% of the patients with the Silzone valve experienced such leaks, as opposed to .25% of patients with conventional valves.

The same day it became aware of the conclusions of the AVERT monitoring board, St. Jude began a voluntary recall of all non-implanted Silzone valves, and so informed the FDA. In response, the FDA, in a letter from Edwin Dee to St. Jude, stated, "We agree with your firm's decision to recall [the Silzonevalve] . . . We have reviewed your action, and conclude that it meets the formal definition of a 'Recall'". This is significant, as your action is an alternative to a Food and Drug Administration legal action to remove the defective products from the market." It is undisputed, however, that the FDA never formally withdrew its PMA approval of the valve, and that the valve had FDA approval on the date it was implanted in each of the plaintiffs.

Plaintiffs filed these suits against St. Jude based on theories of liability including, but not limited to, negligence, product liability, and breach of warranty. St. Jude filed a motion for summary judgment, contending that the plaintiffs' state-court tort claims were preempted by the FDA's federal regulation over the valves at issue. The trial court agreed and granted St. Jude's motion for summary judgment.

Analysis

In *Baker v. St. Jude Medical, Inc.*, No. 01-02-00802-CV (Tex.App.-Houston [1st Dist.] June 30, 2005, no pet. h.), which we issue concurrently with this opinion, this Court considered the same arguments as those in these appeals. Specifically, the Court addressed the issue of whether the

plaintiffs' claims in that case were preempted by St. Jude's compliance with applicable FDA pre-market approval procedures. On a record that is nearly identical to that before us in these appeals, this Court concluded that the plaintiffs' negligence, products liability, deceptive trade practices, fraud, and malice claims were, in fact, preempted by St. Jude's compliance with the FDA's pre-market approval process for the manufacture and distribution of the heart valve that was implanted in the plaintiff. See Baker, slip op. at 18, 21. Accordingly, we affirmed the summary judgment granted in favor of St. Jude. *Id.* at 21.

This Court's opinion in *Baker v. St. Jude* extensively discusses the Court's reasoning behind its conclusion that the doctrine of preemption applies. Neither the briefing nor the record in these appeals shows a reason to distinguish the present cases from Baker.

Accordingly, for the reasons given in *Baker v. St. Jude*, we overrule plaintiffs' sole issue on appeal. Because we have held that all of plaintiffs' claims against St. Jude are preempted by federal law, we affirm the judgments.

APPENDIX D

[LOGO] COURT OF APPEALS FOR THE
FIRST DISTRICT OF TEXAS AT HOUSTON

NOTICE OF ORDER ON MOTION

Cause number: 01-02-00802-CV

Style: Ian Baker, ind. & Representative of Estate of Jean Baker v St. Jude Medical S.C.; St. Jude Medical, Inc.

Date motion filed: July 15, 2005

Type of motion: Motion for rehearing

Party filing motion: Appellant

Document to be filed: _____

If motion to extend time:

Deadline to file document: _____

Number of previous extensions granted: _____

Length of extension sought: _____

Ordered that motion is:

☐ Granted
If document is to be filed, document due:

☐ The Clerk is instructed to file the document as of the date of this order

☐ Absent extraordinary circumstances, the Court will not grant additional motions to extend time

☑ Denied

☐ Dismissed (e.g., want of jurisdiction, moot)

Judge's signature: /s/ Sherry Radack

☑ Acting individually ☐ Acting for the Court

Panel consists of Chief Justice Radack Justices Jenning and Higley.

Date: February 08, 2006

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* Absent emergency or a statement that the motion is unopposed, must wait ten days before acting on motion except for motion to extend time to file a brief. *See* TEX. R. APP. P. 10.3(a).

Note: Single justice may grant or deny any request for relief properly sought by motion, except in a civil case a single justice should not: (1) act on a petition for an extraordinary writ or (2) dismiss or otherwise determine an appeal or a motion for rehearing. TEX. R. APP. P. 10.4(a).

APPENDIX E

IN THE SUPREME COURT OF THE UNITED STATES

No. 06-179

CHARLES R. RIEGEL AND DONNA S. RIEGEL,
Petitioners,

v.

MEDTRONIC, INC.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

PAUL D. CLEMENT
Solicitor General
Counsel of Record
PETER D. KEISLER
Assistant Attorney General
EDWIN S. KNEEDLER
Deputy Solicitor General
MALCOLM L. STEWART
Assistant to the Solicitor General
DOUGLAS N. LETTER
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Attorneys
Department of Justice
Washington, D.C. 20530-0001
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DANIEL MERON
General Counsel

SHELDON T. BRADSHAW
Associate General Counsel
Department of Health and Human Services
Rockville, MD 20857

QUESTION PRESENTED

Whether, under the express preemption provision in 21 U.S.C. 360k, the Food and Drug Administration's premarket approval of a medical device preempts state-law tort claims relating to the safety or efficacy of the device.

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IN THE SUPREME COURT OF THE UNITED STATES

No. 06-179

CHARLES R. RIEGEL AND DONNA S. RIEGEL,
Petitioners,

v.

MEDTRONIC, INC.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

**BRIEF FOR THE UNITED STATES
AS AMICUS CURIAE**

This brief is filed in response to the Court's order inviting the Solicitor General to file a brief expressing the views of the United States. In the view of the United States, the decision of the court of appeals is correct and does not warrant review by this Court.

STATEMENT

1. This case presents the question whether premarket approval of a Class III medical device by the Food and Drug Administration (FDA) preempts state-law tort claims premised on allegations that the device in question is unsafe or ineffective. The device at issue in this litigation—the Evergreen Balloon Catheter—is a medical device regulated by the FDA pursuant to the Medical Device Amendments of 1976 (MDA), 21 U.S.C. 360c *et seq.*, to the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.* The FDCA identifies three classes of medical devices, each subject to a

different level of regulation. See 21 U.S.C. 360c(a)(1); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476-477 (1996). The Evergreen Balloon Catheter is a Class III device, see 21 U.S.C. 360c(a)(1)(C), and is accordingly subject to the most stringent regulatory controls. With exceptions that are not implicated here, the manufacturer of a Class III device must obtain FDA approval of a premarket approval (PMA) application before marketing the device. See 21 U.S.C. 360e(a) (2000 & Supp. IV 2004); *Lohr*, 518 U.S. at 477.[1]

In order to obtain premarket approval for a Class III medical device, a manufacturer must submit a PMA application containing full reports of investigations of the device's safety and effectiveness; a statement of the components and principles of operation of the device; a comprehensive description of the methods of manufacture, processing, packing, and installation of the device; and the proposed labeling for the device. See 21 U.S.C. 360e(c)(1); 21 C.F.R. 814.20. In determining whether to approve a PMA application, the FDA considers the information submitted by the manufacturer as well as other information known to the agency. See 21 C.F.R. 814.45(c). The FDA may also request additional information from the manufacturer, and it may consult with a scientific advisory committee made up of outside experts. 21 C.F.R.

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[1] As the Court explained in *Lohr*, see 518 U.S. at 477-478, two categories of Class III devices may be marketed without PMA approval by the FDA. First, devices that were already being marketed for use at the time of the MDA's enactment may continue to be marketed until the FDA issues an applicable regulation requiring submission of a PMA. See 21 U.S.C. 360e(a) (2000 & Supp. IV 2004); 21 U.S.C. 360e(b)(1)(A); *Lohr*, 518 U.S. at 477-478. Second, a new device that is "substantially equivalent" to a device that is already lawfully on the market may enter the market through FDA clearance of a premarket submission commonly referred to as a "510(k)." See 21 U.S.C. 360(k); *Lohr*, 518 U.S. at 478. Those provisions of the FDCA do not apply in this case, since the Evergreen Balloon Catheter is a post-MDA device for which PMA approval was required.

14.171, 814.20(b)(13). The agency conducts a rigorous review of requests for premarket approval, devoting an average of 1200 hours to each application. See *Lohr*, 518 U.S. at 477.

The FDA grants premarket approval for a Class III device only if, *inter alia*, the agency finds that there is a "reasonable assurance of safety and effectiveness" when the device is used in accordance with the conditions of use included in the proposed labeling, and that the proposed labeling is neither false nor misleading. 21 U.S.C. 360e(d)(1)(A); see 21 U.S.C. 360e(d)(2)(A), (B) and (D). In determining the safety and effectiveness of a device, the FDA must "weigh[] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. 360c(a)(2)(C). The FDA may impose restrictions on the sale or distribution of the device as a condition of premarket approval, see 21 U.S.C. 360e(d)(1)(B); 21 C.F.R. 814.82, and it may impose device-specific restrictions by regulation, see 21 U.S.C. 360j(e)(1). After a manufacturer has received premarket approval for a Class III medical device, it must submit a supplemental application to the FDA before making any changes to the device that affect the device's safety or effectiveness. See 21 U.S.C. 360e(d)(6); 21 C.F.R. 814.39, 814.80. With narrow exceptions, the manufacturer must receive the FDA's approval before making any such changes.[2]

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[2] For a narrow class of changes, the manufacturer may submit a "Changes Being Effected" application, setting out in detail the proposed change and the data or information that supports it. See 21 C.F.R. 814.39(d). Unless the FDA rejects the "Changes Being Effected" application within a specified period, the manufacturer may implement the proposed change prior to FDA action on the application, see 21 C.F.R. 814.39(d)(1), although the FDA retains the authority to reject the application and to require the manufacturer to stop distributing the product with the change. Among the types of changes that are eligible for a "Changes Being Effected" application are labeling changes that add or strengthen a warning, as well as changes in quality control or manufacturing process

The FDCA contains an express preemption provision. That provision states:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. 360k(a). The FDA is authorized to exempt from preemption certain State or local requirements for a device. See 21 U.S.C. 360k(b).

2. The Evergreen Balloon Catheter is a Class III medical device manufactured by respondent Medtronic, Inc. Pet. App. 3a. It is used during angioplasties to open patients' clogged arteries. *Ibid.* The device received premarket approval from the FDA in 1994. *Ibid.* In 1995 and 1996, the FDA approved respondent's supplemental applications for revised labeling for the device. *Id.* at 3a-4a.

Petitioner Charles Riegel suffered extensive injuries after an Evergreen Balloon Catheter ruptured while he was undergoing angioplasty. Pet. App. 4a. He and his wife, petitioner Donna Riegel, brought suit in federal court against respondent. *Ibid.* Petitioners' complaint alleged negligent design, testing, manufacture, distribution, labeling, marketing, and sale of the catheter; strict liability; breach of express warranty; breach of implied warranty; and loss of consortium. *Id.* at 4a-5a. The district court held that all of petitioners' claims

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that provide additional assurance of purity, identity, strength, or reliability of the device. See 21 C.F.R. 814.39(d)(2).

except those for negligent manufacturing and breach of express warranty were preempted by 21 U.S.C. 360k(a). See Pet. App. 55a-74a. The court subsequently granted respondent's motion for summary judgment on the merits of the non-preempted claims. *Id.* at 75a-91a.

3. The court of appeals affirmed. Pet. App. 1a-54a.

The court of appeals explained that the premarket approval process for Class III medical devices is "lengthy and rigorous," requiring each manufacturer to provide extensive information establishing the safety and effectiveness of its device. See Pet. App. 8a-9a. The court further observed that "[t]here is significant opportunity for interaction between the FDA and the manufacturer over the course of the PMA process," *id.* at 8a, and that the FDA is authorized to impose additional requirements as conditions of premarket approval in order to ensure that the device is safe and effective, *id.* at 9a. The court explained as well that, once the FDA approves an application for premarket approval, federal law requires the manufacturer to comply with the specifications set forth in the application and the approval order. See ibid.

In holding that the bulk of petitioners' claims were preempted, the court of appeals construed the term "requirement" in 21 U.S.C. 360k(a)(1) to encompass product specifications set forth in the PMA application that was submitted by respondents and approved by the FDA. See Pet. App. 26a-28a. The court explained that, if the FDA had viewed respondent's proposed product specifications as inadequate to ensure safety and efficacy, the agency could have imposed additional requirements as conditions of premarket approval. *Id.* at 27a-28a. The court recognized that the approved specifications for the Evergreen Balloon Catheter had been fashioned by respondent rather than devised by the FDA, see *id.* at 28a, but it found that fact to be irrelevant to the preemption analysis. The court explained that, "[o]nce the PMA process is complete, all PMA-approved devices are

subject to the same federal device-specific regulation: complying with the standards set forth in their individual approved PMA applications." *Ibid.*

The court of appeals further held that the imposition of tort liability based on the allegedly defective character of the device would have the practical effect of subjecting the manufacturer to state-law requirements "different from, or in addition to," the federal requirements embodied in the approved PMA application. Pet. App. 32a, 35a-36a. The court noted that the claims held to be preempted "do not rest on the premise that the particular catheter used during Mr. Riegel's angioplasty deviated from the standards contained in the approved PMA application for the Evergreen Balloon Catheter." *Id.* at 32a. Rather, the court explained,

> a verdict in [petitioners'] favor on any of these claims would represent a finding that the Evergreen Balloon Catheter had not adhered to the various state common law duties implicated by those claims, *e.g.*, that its design did not comport with the duty of due care, or that its labeling did not comport with the duty to warn. Such a verdict would clearly differ from the FDA's PMA approval of the device (and its related packaging, labeling, distribution, and so on) as being reasonably safe and effective, and, moreover, from the FDA's prohibition against making any modifications affecting the device's safety and effectiveness without first obtaining FDA approval.

Id. at 33a. The court further noted that its conclusion that such tort claims are preempted is supported by the FDA's position on the preemption question. *Id.* at 37a-38a.

The court of appeals also concluded that the FDA's grant of premarket approval is significantly different, for purposes of preemption analysis, from the substantial-equivalence determination (see note 1, *supra*) that was at issue in *Lohr*. See

Pet. App. 24a-27a. The court noted that premarket approval, unlike a finding of substantial equivalence, reflects the FDA's considered judgment that there is reasonable assurance that the device at issue is safe and effective. See *id.* at 25a. The court further observed that, whereas a substantial-equivalence finding "does not reflect the FDA's determination that the device should 'take any particular form for any particular reason,' the PMA process expressly provides the FDA with the power to require the device to take a particular form in order to be approved as safe and effective." *Id.* at 26a (quoting *Lohr*, 518 U.S. at 493). The court also explained that manufacturers of devices for which a substantial-equivalence finding has been made "have broader latitude to make changes without FDA approval than do manufacturers of PMA [-]approved devices." *Id.* at 26a-27a.[3]

Judge Pooler filed an opinion concurring in part and dissenting in part. Pet. App. 43a-54a. While characterizing the preemption issue presented in this case as a "close question," *id.* at 43a, Judge Pooler would have held that petitioners' claims are not preempted, see *id.* at 50a-53a.

DISCUSSION

The court of appeals correctly held—in accordance with the FDA's interpretation of the FDCA, see Pet. App. 37a-

[3] The court of appeals "agree[d] with the district court's conclusion that [petitioners'] negligent manufacturing claim was not preempted, to the extent that it rested on the allegation that the particular Evergreen Balloon Catheter that was deployed during Mr. Riegel's angioplasty had not been manufactured in accordance with the PMA-approved standards." Pet. App. 35a. The court explained that "[a] jury verdict in [petitioners'] favor on this claim would not have imposed state requirements that differed from, or added to, the PMA-approved standards for this device, but would instead have simply sought recovery for [respondent's] alleged deviation from those standards." *Id.* at 35a-36a. The court of appeals affirmed the district court's grant of summary judgment to respondent on the merits of the negligent-manufacturing claim, however, see *id.* at 38a-43a, and petitioners do not challenge that ruling in this Court.

38a—that the FDA's premarket approval of a Class III medical device imposes federal "requirements" that preclude the imposition of state-law tort liability based on respondent's alleged failure to satisfy inconsistent or additional state-law requirements. The Second Circuit's decision in this case accords with the large majority of federal and state appellate rulings on the question presented here. Although one federal court of appeals and one state supreme court have held that comparable tort claims were not preempted, those decisions predate most of the other cases addressing the question, and they were issued without the benefit of FDA's current judgment that premarket approval of a Class III device imposes federal "requirements" that should be given preemptive effect. In light of those intervening developments, the courts that have previously rejected preemption defenses in this context may reconsider their position in an appropriate case. This case, moreover, would not be an appropriate vehicle in which to address the preemption of state tort suits concerning Class III devices that have received PMA approval. See pp. 14- 15, *infra*. Review by this Court therefore is not warranted.

A. The Decision Of The Court Of Appeals Is Correct

Petitioners contend (Pet. 19-22) that the court of appeals' ruling in this case is inconsistent with this Court's decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). *Lohr*, however, does not govern this case.

1. In *Lohr*, this Court considered the application of the MDA's express preemption provision, 21 U.S.C. 360k, to a tort suit involving a medical device for which the FDA had made a substantial-equivalence determination. See 518 U.S. at 480-481. In rejecting the manufacturer's claim that the suit was preempted, the Court explained that the process by which substantial-equivalence findings are made "is by no means comparable to the PMA process," involving an average of 20 hours of review time in contrast to the 1200 hours spent on the average PMA review. *Id.* at 478-479. The Court

also noted the FDA's own admonition that its substantial-equivalence determination "should not be construed as an endorsement of the [device]'s safety." *Id.* at 480.

The manufacturer in *Lohr* argued that the FDA's promulgation of general standards for labeling and manufacturing of medical devices "pre-empts any and all common-law claims brought by an injured plaintiff against a manufacturer of medical devices." 518 U.S. at 486 (plurality opinion). All Members of this Court agreed that the statute does not impose that blanket prohibition on the imposition of state-law tort liability. See *id.* at 487 (plurality opinion); *id.* at 505 (Breyer, J., concurring in part and concurring in the judgment); *id.* at 513 (O'Connor, J., concurring in part and dissenting in part). The manufacturer also argued, inter alia, that the FDA's clearance of a device based on a substantial-equivalence determination preempted suits alleging that the device was defectively designed. See *id.* at 492 (opinion of the Court). In rejecting that contention, the Court explained that "[t]he company's defense exaggerates the importance of the [substantial-equivalence] process," *ibid.*, and that the device at issue had "never been formally reviewed [by the FDA] under the MDA for safety or efficacy," *id.* at 493. Accord *id.* at 513 (O'Connor, J., concurring in part and dissenting in part).

A four-Justice plurality of the *Lohr* Court predicted that any common-law suits preempted by Section 360k would be "few" and "rare." 518 U.S. at 502. In his concurring opinion, however, Justice Breyer stated that "ordinarily, insofar as the MDA preempts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care imposed by a state-law tort action." *Id.* at 504-505. Justice Breyer further stated that he was "not convinced that future incidents of MDA pre-emption of common-law claims will be 'few' or 'rare.'" *Id.* at 508. The remaining four Justices "conclude[d] that state common-law damages

actions do impose 'requirements' and are therefore pre-empted where such requirements would differ from those imposed by the [FDCA]." *Id.* at 509 (O'Connor, J., concurring in part and dissenting in part). Those Justices also expressed disagreement with the plurality's forecast that instances of such preemption would be "rare." *Ibid.* Thus, five Members of the Court in *Lohr* agreed that state tort suits are preempted on essentially the same terms as state prescriptive requirements.

The Court in *Lohr* also noted the significant role of the FDA in defining the MDA's preemptive scope. The Court explained:

> Because the FDA is the federal agency to which Congress has delegated its authority to implement the provisions of the Act, the agency is uniquely qualified to determine whether a particular form of state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941), and, therefore, whether it should be pre-empted.

518 U.S. at 496 (footnote omitted). The Court concluded that, with respect to the construction of the FDCA's express preemption provision, "[t]he ambiguity in the statute—and the congressional grant of authority to the agency on the matter contained within it—provide a sound basis for giving substantial weight to the agency's view of the statute." *Ibid.* (citation and internal quotation marks omitted).

2. In the instant case, the court of appeals held that the FDA's premarket approval of the Evergreen Balloon Catheter imposed specific federal "requirements" that preempted inconsistent duties sought to be imposed through application of state tort law. See Pet. App. 25a-29a. That holding is correct and is consistent with this Court's decision in *Lohr*.

The FDA's premarket approval for the Evergreen Balloon Catheter was premised on the agency's finding that there was reasonable assurance that the device was safe and effective under the conditions of use prescribed, recommended, or suggested in the labeling of the device and that the labeling was neither false nor misleading. 21 U.S.C. 360c(a)(2)(B), 360e(d)(1)(A) and (2)(A)-(E); see Pet. App. 25a, 27a-28a. Once the device was approved, moreover, respondent could not lawfully implement any changes that would affect the safety or efficacy of the device without submitting a supplemental application to the FDA (and, in most instances, receiving prior FDA approval). See *id.* at 26a; p. 3 and note 2, *supra*. Because the specifications contained in respondent's application were binding on the manufacturer once the application had been approved, and because the FDA's PMA approval reflected the agency's considered judgment as to the product's safety and efficacy, the court of appeals correctly held that those specifications constitute federal "requirement[s]" within the meaning of Section 360k(a)(1).

Moreover, in determining the safety and effectiveness of a device, the FDA must "weigh[] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. 360c(a)(2)(C). The court of appeals' ruling thus is fully consistent with *Lohr*, in which the Court distinguished the facts before it from a case, such as this one, "in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers." 518 U.S. at 501.

As the court of appeals explained, if the FDA had determined that the device as described in respondent's application was not safe and effective, the agency could have conditioned its grant of premarket approval on respondent's agreement to

undertake specified modifications. Pet. App. 27a-28a. A product specification devised by the FDA and imposed as a condition of authority to market a medical device would constitute a federal "requirement" that would preempt state efforts to impose inconsistent or additional common-law duties. The court of appeals correctly recognized that respondent should not be subject to *greater* potential tort liability simply because the FDA had "deemed the PMA application for the Evergreen Balloon Catheter acceptable in its present form" and therefore had declined to impose additional conditions. *Id.* at 28a.

The FDCA also specifically addresses the possibility that new information might come to light that would call into question whether a previously approved device meets the Act's requirements for PMA approval. Once again, however, the FDCA vests responsibility for taking action in the FDA, based on its evaluation of the information and weighing of the relevant considerations. The Act thus authorizes the FDA to withdraw its PMA approval of a device if the agency finds that the device is unsafe or ineffective, or if the agency finds, on the basis of new information evaluated together with information available to it when it approved the application, that the requisite showing of reasonable assurance that the device is safe and effective is lacking, or that the labeling is false or misleading in any particular and was not corrected within a reasonable time after receipt from the FDA of notice of that fact. See 21 U.S.C. 360e(e)(1)(A), (B) and (F). Where the FDA has not taken such action, its approval of the PMA—and the "requirements" that result from that approval—remain in effect.

The court of appeals also correctly held that petitioners' tort suit seeks to impose state "requirement[s]," within the meaning of Section 360k(a), that relate to safety or efficacy and are different from the federal requirements that apply to the Evergreen Balloon Catheter. See Pet. App. 30a-35a. As

the court of appeals recognized, this Court in construing similarly worded federal preemption provisions "has held firm to the view that state 'requirements' can be created by state common law actions." *Id.* at 31a; see, *e.g.*, *Bates v. Dow Agroscis. LLC*, 544 U.S. 431, 443 (2005); see also *Lohr*, 518 U.S. at 503-504 (Breyer, J., concurring in part and concurring in the judgment); *id.* at 510-512 (O'Connor, J., concurring in part and dissenting in part). The claims that the court of appeals held to be preempted do not rest on the premise that the particular catheter used during Mr. Riegel's angioplasty deviated from the specifications in the approved PMA application. Rather, they all rest on the allegation that the Evergreen Balloon Catheter, in the form approved by the FDA, "is in some way defective and therefore requires modification." Pet. App. 32a. A verdict in petitioners' favor would necessarily reflect a finding that respondent could comply with applicable state-law duties of care only by altering the product specifications or labeling that had been reviewed and approved by the FDA. Imposition of tort liability on the basis of such a finding would entail the application of state-law requirements that are "different from, or in addition to," 21 U.S.C. 360k(a)(1), the federal requirements applicable to the device, and that "relate[] to the safety or effectiveness of the device," 21 U.S.C. 360k(a)(2).

The FDA is the expert agency charged by Congress with balancing the risks and benefits of medical devices under the FDCA, and the accomplishment of its regulatory goals would be undermined if lay judges or juries were permitted to second-guess the scientific judgments it makes in approving a PMA application. When the FDA has concluded that a particular medical device is safe and effective for use and has approved the device for marketing, it would undermine the regulatory scheme established by Congress for a jury adjudicating a state-law claim to determine that the same device is defectively designed. Similarly, when the FDA concludes that a particular warning label strikes an appropriate balance

between properly notifying users of potential dangers and ensuring that beneficial and possibly life-saving uses of the device are not deterred, a jury should be precluded from deciding that different warnings ought to have been given.

3. In *Bates*, this Court construed the preemption provision of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which provides that a State "shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." 7 U.S.C. 136v(b) (quoted in *Bates*, 544 U.S. at 439). FIFRA prohibits the sale of "misbranded" products and states that a pesticide is misbranded if its labeling contains "false or misleading" statements, "does not contain adequate instructions for use," or "omits necessary warnings." *Bates*, 544 U.S. at 438. That misbranding prohibition applies to pesticides that are registered with the Environmental Protection Agency (EPA). *Ibid.* The Court held in *Bates* that FIFRA did not preempt the plaintiffs' state-law damages claim alleging a tortious failure to warn so long as the elements of the state cause of action were substantively equivalent to FIFRA's prohibition on the sale of "misbranded" products. See *id.* at 447. The Court "emphasize[d]," however, that "a state-law labeling requirement must in fact be equivalent to a requirement under FIFRA in order to survive pre-emption." *Id.* at 453.

The FDCA also prohibits the distribution of misbranded devices, see 21 U.S.C. 331(a)-(c), and a device is deemed misbranded if, *inter alia*, "its labeling is false or misleading in any particular," or the device "is dangerous to health when used in the * * * manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. 352(a) and (j). The misbranding prohibition applies to products that have received PMA approval. The federal requirements that result from the PMA process have preemptive effect, however, and as explained below, the

possibility of federal misbranding liability does not alter that result. See pp. 15-16, *infra*. In any event, petitioners in their certiorari petition do not advance the theory that their state-law claims are preserved because the relevant state-law requirements parallel the FDCA's misbranding provisions. Cf. note 4, *infra*. Indeed, petitioners do not even cite the FDCA's misbranding provisions. Nor did the court of appeals address that issue; it considered only whether the PMA approval process itself results in "requirement[s]" under 21 U.S.C. 360k(a), and whether state common law imposes corresponding state "requirement[s]." This case therefore would not present an occasion for the Court to consider the viability of such a theory.

Such a theory would be unavailing in any event. The process of agency review under FIFRA with regard to the label language at issue in *Bates* differs in important respects from the process by which the FDA decides whether to grant premarket approval for particular Class III devices. The plaintiff farmers in *Bates* alleged that the label of a pesticide manufactured by the defendant had failed to warn of the potential for the pesticide to damage the farmers' peanut crops. See 544 U.S. at 434-435. Under FIFRA, EPA reviews pesticides and their labeling to determine whether the pesticide causes unreasonable adverse effects on human health or safety or the environment, but EPA does not evaluate the efficacy of the product, including its potential to harm crops or cause other property damage, and the agency does not review the accuracy of any statements about efficacy on the proposed labeling for the product. *Id.* at 440. EPA therefore had not determined whether the label at issue in *Bates* had adequately warned farmers of the potential for damage to their crops. See *ibid.* (noting that EPA had "never passed on the accuracy of the statement in [the pesticide's] original label recommending the product's use 'in all areas where peanuts are grown"). In the instant case, by contrast, petitioners' challenge to the safety and efficacy of the Evergreen Balloon Catheter goes

directly to matters as to which the FDA conducted a rigorous agency review in the PMA process—a review that culminated in the FDA's finding that the Evergreen Balloon Catheter *does* provide "reasonable assurance of safety and effectiveness" and that the labeling is not "false or misleading." See 21 U.S.C. 360e(d)(1)(A).[4]

Furthermore, the Court explained in *Bates* that FIFRA does not have a comprehensive goal of "uniformity," but rather "authorizes a relatively decentralized scheme that preserves a broad role for state regulation." 544 U.S. at 450. Under the FDCA, by contrast, the FDA is vested with centralized authority in order to promote uniformity of regulation, including the authority under 21 U.S.C. 360k(b) to decide whether exceptions to preemption of state law should be allowed.

4. In its amicus brief filed at the petition stage at the Court's invitation in *Smith Industries Medical Systems, Inc. v. Kernats*, cert. denied, 522 U.S. 1044 (1998), the United States took the position that the FDA's grant of premarket approval for a medical device does not itself establish federal "requirement[s]" for the device within the meaning of Section

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[4] As a general matter, 21 U.S.C. 360k(a) does not preempt common-lawsuits in which the duty of care is defined by federal law and a State simply provides additional remedies for violations of the federal standard. See *Lohr*, 518 U.S. at 494-497; *id.* at 513 (O'Connor, J., concurring in part and dissenting in part). Consistent with that principle, the court of appeals correctly held that petitioners' "negligent manufacturing claim was not preempted, to the extent that it rested on the allegation that the particular Evergreen Balloon Catheter that was deployed during Mr. Riegel's angioplasty had not been manufactured in accordance with the PMA-approved standards." Pet. App. 35a; see note 3, *supra*. Adjudication of the negligent-manufacturing claim would not implicate any FDA finding, since the agency has made no individualized determination whether a particular catheter conforms to the approved product specifications. With respect to the adequacy of the product specifications themselves, however, the FDA found that there was reasonable assurance of safety and effectiveness of the device, and that the labeling was not false or misleading, when it approved respondent's PMA application.

360k(a). U.S. Br. at 14-17, *Kernats, supra* (No. 96-1405). The position taken in the government's brief in *Kernats* was based upon the FDA's interpretation of the MDA and the agency's characterization of its role in the administrative process at that time, as reflected in a proposed interpretive rule that was appended to the brief and published shortly after the brief was filed. See 62 Fed. Reg. 65,384, 65,387 (1997). That proposed rule, however, was subsequently withdrawn. See 63 Fed. Reg. 39,789 (1998).

The FDA has since reexamined the issue and determined that the position it announced at the time of the filing in *Kernats* was erroneous. The FDA's current position was set forth in an amicus brief filed by the United States on May 14, 2004, in *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004). See *Horn*, 376 F.3d at 170-173 (discussing the FDA's position set forth in the amicus filing). The government explained in the amicus brief in *Horn* that the prior position did not adequately reflect either the highly detailed nature of the process by which the FDA reviews applications for premarket approval, or the constraints that premarket approval places on manufacturers who subsequently wish to change a device's specifications. U.S. Amicus Br., *Horn v. Thoratec, supra*, at 28 (No. 02-4597); see generally *id.* at 6-11, 15-17, 20-21, 25-27. The government's position in *Kernats* is also inconsistent with the risk-management principles that the FDA currently follows, which recognize that over-warning may be detrimental to the public health. See, *e.g., id.* at 29; 71 Fed. Reg. 3935 (2006) (explaining that additional state requirements governing disclosure of drug-risk information "can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use," and that "[e]xaggeration of risk could discourage appropriate use of a beneficial drug"). This Court held in *Lohr* that the FDA's views on preemption questions under 21 U.S.C. 360k are entitled to "substantial weight." 518 U.S. at 496.

B. The Decision Of The Court Of Appeals Does Not Warrant Review

The Second Circuit's resolution of the preemption question raised in this case is consistent with the rulings of the great majority of federal and state appellate courts that have addressed the issue since *Lohr*. During that period, all but one of the federal courts of appeals to decide the issue have held that premarket approval of a medical device preempts state tort claims challenging the safety or efficacy of a product that was designed, manufactured, and labeled in compliance with the terms of the premarket approval order. See Pet. App. 24a-38a; *Horn*, 376 F.3d at 166-180; *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 486-490 (7th Cir. 2005), cert. denied, 126 S. Ct. 1464 (2006); *Martin v. Medtronic, Inc.*, 254 F.3d 573, 575-585 (5th Cir. 2001), cert. denied, 534 U.S. 1078 (2002); *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 221-237 (6th Cir. 2000), cert. denied, 534 U.S. 818 (2001); see also *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 791-799 (8th Cir. 2001) (en bane) (finding federal preemption based on approval of device pursuant to regulatory precursor of premarket approval process), cert. denied, 535 U.S. 1056 (2002); but see *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1369-1382 (11th Cir. 1999) (holding that comparable claims were not preempted). Similarly, all but one of the state supreme courts to rule on this issue have held that analogous suits are preempted by federal law. See *Green v. Dolsky*, 685 A.2d 110, 115-118 (Pa. 1996), *cert. denied*, 520 U.S. 1168, and 520 U.S. 1212 (1997); *Fry v. Allergan Med. Optics*, 695 A.2d 511, 514-517 (R.I.), cert. denied, 522 U.S. 952 (1997); *Worthy v. Collagen Corp.*, 967 S.W.2d 360, 366-377 (Tex.), cert. denied, 524 U.S. 954 (1998); but see *Weiland v. Telectronics Pacing Sys., Inc.*, 721 N.E.2d 1149, 1151-1154 (Ill. 1999).[5]

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[5] Petitioners contend that three additional cases are in conflict with the weight of authority holding that the FDA's premarket approval of a medical device preempts state tort claims under Section 360k(a). See Pet. 3

Moreover, the decisions in *Goodlin* and *Weiland*, which rejected preemption defenses similar to that raised by respondent here, were issued in 1999, when the law in this area was relatively undeveloped and when the stated view of the FDA, as set forth in the amicus brief filed by the United States in *Kernats* (see pp. 16-17, *supra*), was that the PMA approval process does not impose "requirement[s]" under 21 U.S.C. 360k(a) and that claims like petitioners' were not preempted. Since that time, several federal courts of appeals and state supreme courts have sustained analogous preemption defenses, and no such court has issued a contrary ruling. And since that time, the FDA has reassessed the issue and has concluded that the PMA approval process does result in "requirements" and that state tort claims challenging the safety or efficacy of PMA-approved devices are therefore preempted under 21 U.S.C. 360k(a). See p. 17, *supra*.

The courts in *Goodlin* and *Weiland* had no opportunity to take into account the later-developing majority view among the federal and state appellate courts. Nor did the courts in *Goodlin* and *Weiland* have the opportunity to consider the current position of the FDA, the expert agency charged by Congress with administering the FDCA. In any future decision concerning Section 360k's preemptive scope, those courts would be required to give "substantial weight" to the FDA's position. *Lohr*, 518 U.S. at 496.

(citing *Oja v. Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997), and *Niehoff v. Surgidev Corp.*, 950 S.W.2d 816 (Ky. 1997), cert. denied, 523 U.S. 1005 (1998)); Pet. 14 (citing *State ex rel. Miller v. New Womyn, Inc.*, 679 N.W.2d 593 (Iowa 2004)). Those cases are readily distinguishable. None of them involved devices for which the FDA had approved a PMA application before the conduct that was alleged to be the basis for liability. See *Oja*, 111 F.3d at 787, 789; *Niehoff*, 950 S.W.2d at 817; *New Womyn*, 679 N.W.2d at 597. In *Oja* and *Niehoff*, moreover, the courts held that liability under state tort law or other state law of general applicability would not result in the imposition of a state "requirement," see *Oja*, 111 F.3d at 789; *Niehoff*, 950 S.W.2d at 822—a premise that was subsequently rejected by this Court in *Bates*, see 544 U.S. at 443; p. 12, *supra*.

In light of those intervening developments, the Eleventh Circuit and the Illinois Supreme Court may reconsider their earlier approach should this issue arise in future cases litigated within those jurisdictions. Under these circumstances, the narrow split in authority does not warrant this Court's review. This Court has repeatedly denied certiorari petitions that presented questions concerning the preemptive effect of the FDA's issuance of premarket approval for Class III medical devices. See *McMullen v. Medtronic, Inc.*, 126 S. Ct. 1464 (2006); *Knisley v. Medtronic, Inc.*, 126 S. Ct. 420 (2005); *Brooks v. Howmedica, Inc.*, 535 U.S. 1056 (2002); *Martin v. Medtronic, Inc.*, 534 U.S. 1078 (2002); *Kemp v. Medtronic, Inc.*, 534 U.S. 818 (2001); *Worthy v. Collagen Corp.*, 524 U.S. 954 (1998); *Fry v. Allergan Med Optics*, 522 U.S. 952 (1997); *Green v. Dolsky*, 520 U.S. 1168 (1997); *Collagen Corp. v. Green*, 520 U.S. 1212 (1997). There is no reason for a different result here.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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May 2007